

US3462213 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:42:58

All time stamps listed in this document are displayed in GMT

US3462213

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:02:18

Generated On: 09 Jun 2021 17:42:58

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Participant ID

US3462213

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

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US3462213

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:36:49

Generated On: 09 Jun 2021 17:42:58

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
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) 13 Feb 2021 01:36:49

Generated On: 09 Jun 2021 17:42:58

Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:36:49

Generated On: 09 Jun 2021 17:42:58

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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) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

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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) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	SEASONAL ALLERGIC RHINITIS
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 (2)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	ASTHMA (MODERATE)
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) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN NOV 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)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462213

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	OCCASIONAL CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	APPENDICITIS
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	LEFT BREAST NODULE
Start date (dd MMM yyyy)	UN JAN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	OCCASIONAL HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	SHINGLES
Start date (dd MMM yyyy)	29 MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	04 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	DIABETES II (DIET CONTROLLED)
Start date (dd MMM yyyy)	UN APR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	HYPERPLASTIC THYROID NODULE
Start date (dd MMM yyyy)	UN JAN 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 (14)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	OCCASIONAL BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	UN OCT 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	LUMBAR DISC BULGE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	SULFA ALLERGY (HIVES)
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	INJECTED IODINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462213

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	LEFT KNEE PAIN
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)	_____

US3462213

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	BENIGN FATTY ABDOMINAL TUMOR
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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



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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	ABDOMINIAL FATTY TUMOR REMOVED
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

US3462213

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	APPENDECTOMY
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

US3462213

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

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Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

US3462213

Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

Condition	PERENNIAL ALLERGIC RHINITIS
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 (33)

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

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



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:04
Height (xxx.x)	148 cm
Weight (xxx.x)	67.8 kg
BMI (xxx.x)	30.95325 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:36:49

Generated On: 09 Jun 2021 17:42:58

Date of assessment (dd MMM yyyy) 17 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) UN UNK 1998

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

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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

US3462213

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

<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>	

US3462213

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186699

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Height	ND - Not Done
Weight	ND - Not Done



US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:04
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:35
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462213

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 AUG 2020

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 14:57

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3462213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

17 AUG 2020 14:30

US3462213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:32	17 AUG 2020 14:32
Nasopharyngeal Swab 2	No		

US3462213

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 15:38

PC Open Date & Time

17 AUG 2020 15:17

PC Close Date & Time

17 AUG 2020 17:47



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

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

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

PC Time Stamp 17 AUG 2020 22:51

PC Open Date & Time 17 AUG 2020 18:42

PC Close Date & Time 18 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

18 AUG 2020 23:46

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 00:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

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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

97.5 °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

21 AUG 2020 23:07

---

PC Open Date & Time

21 AUG 2020 12:00

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PC Close Date & Time

22 AUG 2020 11:59

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US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.0 °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

23 AUG 2020 00:02

---

PC Open Date & Time

22 AUG 2020 12:00

---

PC Close Date & Time

23 AUG 2020 11:59

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US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

24 AUG 2020 09:17

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 15:39

PC Open Date & Time

17 AUG 2020 15:17

PC Close Date & Time

17 AUG 2020 17:47



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 22:52

PC Open Date & Time

17 AUG 2020 18:42

PC Close Date & Time

18 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 23:47

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 00:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b> Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/> No <input type="radio"/>
Please record - <b>REDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site redness with the ruler provided.	
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/> No <input type="radio"/>
Please record - <b>SWELLING/HARDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b> Please select one response below	None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 23:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 00:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 09:17

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 15:40
PC Open Date & Time	17 AUG 2020 15:17
PC Close Date & Time	17 AUG 2020 17:47

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 22:53
PC Open Date & Time	17 AUG 2020 18:42
PC Close Date & Time	18 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 23:48
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 00:05
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 23:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 00:03
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 09:18
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3462213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3462213

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	12:51 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:51
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	TYMPANIC
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG



US3462213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 SEP 2020

What was the treatment time? (00:00-23:59) 12:14 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 12:14

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

US3462213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	12:10 (24 HR)
Collection date and time (derived)	30 SEP 2020 12:10

US3462213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:12	30 SEP 2020 12:12
Nasopharyngeal Swab 2	No		

US3462213

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 30 SEP 2020 12:53

PC Open Date & Time 30 SEP 2020 12:34

PC Close Date & Time 30 SEP 2020 15:04

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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 30 SEP 2020 23:24

PC Open Date & Time 30 SEP 2020 15:59

PC Close Date & Time 01 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 OCT 2020 23:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

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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

05 OCT 2020 11:18

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PC Open Date & Time

04 OCT 2020 12:00

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PC Close Date & Time

05 OCT 2020 11:59

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US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 6

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

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

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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

05 OCT 2020 22:10

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 7

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

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

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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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 23:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:54

PC Open Date & Time

30 SEP 2020 12:34

PC Close Date & Time

30 SEP 2020 15:04

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 23:25

PC Open Date & Time

30 SEP 2020 15:59

PC Close Date & Time

01 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 23:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 11:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 22:11

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 23:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 12:54
PC Open Date & Time	30 SEP 2020 12:34
PC Close Date & Time	30 SEP 2020 15:04

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 23:25
---------------	-------------------

PC Open Date & Time	30 SEP 2020 15:59
---------------------	-------------------

PC Close Date & Time	01 OCT 2020 11:59
----------------------	-------------------

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 23:01
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 11:19
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 22:11
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 23:13
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3462213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

DUE TO VISIT 2 OCCURRING SO  
LATE, DAY 43 PHONE CALL  
AND VISIT 3 HAPPENED ON THE  
SAME DATE. PATIENT WAS  
SEEN IN OFFICE.



US3462213

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

CONTACT WAS MISSED DUE TO  
CONFUSION REGARDING LATE  
VISIT 2.

If Contact Not Made, please provide Comments

US3462213

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:33

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3462213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

14 OCT 2020 12:00

US3462213

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:36:50

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 22:07:24

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**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

16 NOV 2020 17:52:00

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 11:52:56
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 103

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

No ☒

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 NOV 2020 17:35:13

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59



US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 00:04:36

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 19:36:24

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	16 DEC 2020 18:52:25
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 14:27:16

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 00:02:28

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	06 JAN 2021 10:26:28
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 11:40:38

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 08:24:10
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59



US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 JAN 2021 11:48:10
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 18:46:52

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 18:48:51
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 FEB 2021 15:51:12
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	26 FEB 2021 20:00:32
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	04 MAR 2021 09:10:22
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 17:22:19

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 12:02:48

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 15:15:14

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 12:00:51

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

<b>TIMEPOINT</b>	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 <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	07 APR 2021 08:14:20
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 243

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

No ☒

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

14 APR 2021 21:47:04

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 08:17:23

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59
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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 432

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

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

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

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

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 439

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 453

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 530

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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 ☐

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 MAR 2022 23:59
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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 705

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 OCT 2022 23:59

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US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3462213**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

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

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[Patient Cloud Open Date & Time](#)

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3462213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:42:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 10:44:29

US3462213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:12:14

Generated On: 09 Jun 2021 17:42:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462213

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:12:14

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:07:23

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:37:42

Generated On: 09 Jun 2021 17:42:58

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462213

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:07:23

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3462213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:07:23

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

12 MAR 2021 09:40

US3462213

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:07:23

Generated On: 09 Jun 2021 17:42:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3462213**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3462213**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462213

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:42:58

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

**US3462213**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:42:58**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3462213

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3462213

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:12:14

Generated On: 09 Jun 2021 17:42:58

Date of updated informed consent (dd MMM yyyy) 5 FEB 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) 5 FEB 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 \_\_\_\_\_

US3462213

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:02:19

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 FEB 2021
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	5 FEB 2021 11:25

US3462213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:02:18

Generated On: 09 Jun 2021 17:42:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 FEB 2021
Collection time (00:00 - 23:59)	11:17
Collection Date and Time (derived)	5 FEB 2021 11:17

US3462213

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:02:18

Generated On: 09 Jun 2021 17:42:58

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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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US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

AEID	USA-US093-2021-MRNA-1273-P30 1000001
Adverse event	NONARTERITIC ISCHEMIC OPTIC NERVE NEURITIS (RIGHT EYE)
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)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 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)	4 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	9 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	352 of 2680

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		False
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input type="radio"/>
	Recovered/Resolved with Sequelae	<input checked="" type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	IMPAIRED VISION RIGHT EYE	
<hr/>		
Narrative		

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

---

SUBJECT INITIALLY REPORTED  
TO SITE AN AE OF RIGHT EYE  
SWOLLEN OPTIC NERVE,  
STARTING ON 15DEC2020.  
SUBJECT WAS STARTED ON  
PREDNISOLONE EYE DROPS (1  
DROP PER DAY). ON 04JAN2021,  
SUBJECT'S VISION  
DETERIORATED FURTHER, AND  
SHE WAS INSTRUCTED BY HER  
OPHTHALMOLOGIST TO GO TO  
THE ER. SUBJECT WAS  
ADMITTED TO THE HOSPITAL  
ON 04JAN2021 FOR TESTING.  
SUBJECT'S SYMPTOMS  
INCLUDED EYE IRRITATION,  
BLURRY VISION, AND A "DARK  
SPOT" IN HER VISION. PATIENT  
REPORTED NO EYE PAIN.  
BRAIN ANGIOGRAM WAS  
UNREMARKABLE.  
ECHOCARDIOGRAM AND  
BRAIN MRI WERE NORMAL.  
PATIENT WAS DISCHARGED TO  
HOME ON 09JAN2021 ON ORAL  
CORTICOSTEROID BURST.  
DIAGNOSIS UPON DISCHARGE  
WAS NONARTERITIC ISCHEMIC  
OPTIC NERVE NEURITIS -  
RIGHT EYE.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3462213

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

AEID

Adverse event

SWOLLEN OPTIC NERVE RIGHT  
EYE

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)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 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 ☐

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US3462213

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	

US3462213

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

AEID	
Adverse event	LARYNGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

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

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:02:18

Generated On: 09 Jun 2021 17:42:58

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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.

---



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 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 (2)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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 (3)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication SYMBICORT 160/4.5

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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Name of Medication PRILOSEC

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2005
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) 09 Apr 2021 13:13:03

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Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL AND PERENNIAL  
ALLERGIC RHINITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2006
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL HEADACHES

Dose per administration 220

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) 09 Apr 2021 13:13:03

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2002	
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)

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Name of Medication GLYCOLAX

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMEN T

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication LIDODERM 5%

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication GAVISCON 80/14.2

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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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 NOV 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 (13)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication MOBIC

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL 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 (13)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 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 (14)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication NORVASC

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 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 (15)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL AND PERENNIAL  
ALLERGIC RHINITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN DEC 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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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Form: Prior/Concomitant Medication and Vaccination (16)

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Name of Medication MAXIDE 37.5/25

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 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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Form: Prior/Concomitant Medication and Vaccination (17)

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Name of Medication PREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE SWOLLEN OPTIC NERVE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify DROP

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)

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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)	15 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 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 (19)

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Name of Medication SOLU-MEDROL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

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)

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 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)		4 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication SOLU-MEDROL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

Dose per administration 250

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

EVERY 6 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (20)

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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 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)	4 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)		9 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) 09 Apr 2021 13:13:03

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:13:03

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Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

Dose per administration 60

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 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)	12 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"/>

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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)		17 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"/>

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 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)		22 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"/>



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT EYE NONARTERITIC  
ISCHEMIC OPTIC NERVE  
NEURITIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 13:13:03

Generated On: 09 Jun 2021 17:42:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Mar 2021 00:58:52

Generated On: 09 Jun 2021 17:42:58

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Mar 2021 00:58:51

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 JAN 2021	CEREBRAL ANGIOGRAM	Adverse Event	
4 JAN 2021	BRAIN MAGNETIC RESONANCE IMAGING	Adverse Event	
4 JAN 2021	COMPUTED TOMOGRAPHY OF HEAD	Adverse Event	
5 JAN 2021	VISUAL ANALOG SCALE: CAROTID DUPLEX BILATERAL	Adverse Event	
5 JAN 2021	VISUAL ANALOG SCALE: TEMPORAL ARTERIES	Adverse Event	
5 JAN 2021	COMPLETE ECHOCARDIOGRAM	Adverse Event	

US3462213

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:58

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

US3462213

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:58

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 13:07:15

Generated On: 09 Jun 2021 17:42:58

SAEID	USA-US093-2021-MRNA-1273-P301000001
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 13:07:15

Generated On: 09 Jun 2021 17:42:58

SAEID	USA-US093-2021-MRNA-1273-P301000001
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/JAN/2021 05:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 13:07:15

Generated On: 09 Jun 2021 17:42:58

SAEID	USA-US093-2021-MRNA-1273-P301000001
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/FEB/2021 08:22
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

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 13:07:15

Generated On: 09 Jun 2021 17:42:58

SAEID	USA-US093-2021-MRNA-1273-P301000001
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/MAR/2021 09:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 13:07:15

Generated On: 09 Jun 2021 17:42:58

SAEID	USA-US093-2021-MRNA-1273-P301000001
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3462213 (Prod: Crisor, LLC)

**US3462213**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:42:58**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:48:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'US3462213'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:54:19

**US3462213**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:03
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	17 Aug 2020 22:11:53

US3462213

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:03
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:54:19

**US3462213**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:03
User entered 'Clinic (Clinic)'	Savannah Peterson (b) (4)	17 Aug 2020 22:11:53



**US3462213**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'SCRN'	System	17 Aug 2020 22:11:53

US3462213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:58

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:54:20

US3462213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '66'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'YEARS'	System	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '66'	System	17 Aug 2020 22:12:57

US3462213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:58

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered 'Female (F)'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Savannah Peterson (b) (4) (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

**White**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered 'I'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22



US3462213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:58

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

US3462213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered empty.	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22

**US3462213**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:42:58**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:38
User entered '0'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:22



US3462213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered '17 Aug 2020'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57

**US3462213**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:42:58**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Aug 2020'	System	17 Aug 2020 22:12:57

**US3462213**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:42:58**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2020'	System	17 Aug 2020 22:12:57

**US3462213**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:42:58**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered 'Amendment 2 (2)'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57

US3462213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:58

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57

US3462213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered empty.	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57

US3462213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered empty.	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57

**US3462213**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:42:58**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered 'No (N)'	Savannah Peterson (b) (4)	17 Aug 2020 22:12:57



US3462213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:54:19

**US3462213**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:42:58**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'I'	System	17 Aug 2020 22:13:10

US3462213

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:42:58

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:53
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	17 Aug 2020 22:13:10

US3462213

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:42:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:28:56
User entered 'Yes (Y)'		03 Oct 2020 18:52:59

US3462213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:50
User closed query 'Please remove Perennial Allergic Rhinitis from here and add as a separate Medical Hx finding on another log line.' (Site from CRA).		22 Jan 2021 21:46:47
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:44:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:44:04
Data point term sent to Coder	System	21 Jan 2021 17:42:50
Query 'Please remove Perennial Allergic Rhinitis from here and add as a separate Medical Hx finding on another log line.' answered with 'Corrected' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:42:17
DataPoint Un-verified.		21 Jan 2021 17:42:06
Coding entries removed.		21 Jan 2021 17:42:06
User entered 'SEASONAL ALLERGIC RHINITIS' reason for change: Data Entry Error		21 Jan 2021 17:42:06
DataPoint Verified.		03 Dec 2020 19:53:48
User opened query 'Please remove Perennial Allergic Rhinitis from here and add as a separate Medical Hx finding on another log line.' (Site from CRA).		03 Dec 2020 19:49:50
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:54:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:54:53
Data point term sent to Coder	System	03 Oct 2020 18:54:04

US3462213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'SEASONAL AND PERENNIAL ALLERGIC RHINITIS'	(b) (4), (b) (6)	03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1998'		03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:53:23



**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1998'	System	03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1998'	System	03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:53:23

**US3462213**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:53:23

US3462213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:51:18
DataPoint Un-verified.		30 Mar 2021 20:51:16
User closed query 'Please specify if Asthma was Moderate or Severe. ' (Site from CRA).		30 Mar 2021 20:51:08
DataPoint Verified.		30 Mar 2021 20:51:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	10 Feb 2021 23:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	10 Feb 2021 23:28:41
Data point term sent to Coder	System	10 Feb 2021 23:27:45
Query 'Please specify if Asthma was Moderate or Severe. ' answered with 'Clarification added.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 23:27:09
DataPoint Un-verified.		10 Feb 2021 23:27:00
Coding entries removed.		10 Feb 2021 23:27:00
User entered 'ASTHMA (moderate)' reason for change: Data Entry Error		10 Feb 2021 23:27:00
DataPoint Verified.		03 Dec 2020 19:53:48
User opened query 'Please specify if Asthma was Moderate or Severe. ' (Site from CRA).		03 Dec 2020 19:50:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 18:54:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	03 Oct 2020 18:54:53
Data point term sent to Coder	System	03 Oct 2020 18:54:05



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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'ASTHMA'	(b) (4), (b) (6)	03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1998'		03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1998'	System	03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1998'	System	03 Oct 2020 18:53:45



**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:53:45

**US3462213**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:53:45

US3462213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:56:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:56:40
Data point term sent to Coder	System	03 Oct 2020 18:56:07
User entered 'HYPERTENSION'	(b) (4), (b) (6)	03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Nov 2017'		03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:55:39



**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Nov 2017'	System	03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2017'	System	03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:55:39

**US3462213**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:55:39

US3462213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 18:56:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 18:56:40
Data point term sent to Coder	System	03 Oct 2020 18:56:07
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1995'		03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:55:59

US3462213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:55:59



**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1995'	System	03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1995'	System	03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:55:59

**US3462213**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:55:59

US3462213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:43
Data point term sent to Coder	System	03 Oct 2020 18:57:07
User entered 'OCCASIONAL CONSTIPATION'	(b) (4), (b) (6)	03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1999'		03 Oct 2020 18:56:14



**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1999'	System	03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1999'	System	03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:56:14

**US3462213**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:56:14



US3462213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:42
Data point term sent to Coder	System	03 Oct 2020 18:57:07
User entered 'APPENDICITIS'	(b) (4), (b) (6)	03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1986'		03 Oct 2020 18:56:45

US3462213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1986'		03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1986'	System	03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1986'	System	03 Oct 2020 18:56:45



**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1986'	System	03 Oct 2020 18:56:45

**US3462213**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1986'	System	03 Oct 2020 18:56:45

US3462213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:57:43
Data point term sent to Coder	System	03 Oct 2020 18:57:07
User entered 'GALLSTONES'	(b) (4), (b) (6)	03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2009'		03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2009'		03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:57:05



**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2009'	System	03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2009'	System	03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2009'	System	03 Oct 2020 18:57:05

**US3462213**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2009'	System	03 Oct 2020 18:57:05

US3462213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Breast mass, LLT: Breast nodule - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 22:48:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 22:48:52
Data point term sent to Coder	System	03 Oct 2020 18:58:09
User entered 'LEFT BREAST NODULE'	(b) (4), (b) (6)	03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Jan 2016'		03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 18:58:03



**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Oct 2019'		03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2016'	System	03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2016'	System	03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Oct 2019'	System	03 Oct 2020 18:58:03

**US3462213**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2019'	System	03 Oct 2020 18:58:03

US3462213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:59:44
Data point term sent to Coder	System	03 Oct 2020 18:59:10
User entered 'UTERINE FIBROIDS'	(b) (4), (b) (6)	03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2005'		03 Oct 2020 18:58:27



**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2010'		03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2005'	System	03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2005'	System	03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2010'	System	03 Oct 2020 18:58:27

**US3462213**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	03 Oct 2020 18:58:27



US3462213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
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)	29 Jan 2021 13:16:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:16:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:52
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)	03 Oct 2020 18:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 18:59:44
Data point term sent to Coder	System	03 Oct 2020 18:59:10
User entered 'OCCASIONAL HEADACHES'	(b) (4), (b) (6)	03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1980'		03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1980'	System	03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1980'	System	03 Oct 2020 18:58:45



**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:58:45

**US3462213**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:58:45

US3462213

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:00:45
Data point term sent to Coder	System	03 Oct 2020 19:00:10
User entered 'SHINGLES'	(b) (4), (b) (6)	03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '29 May 2019'		03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '04 Jun 2019'		03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:59:24



**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'May 2019'	System	03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2019'	System	03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jun 2019'	System	03 Oct 2020 18:59:24

**US3462213**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2019'	System	03 Oct 2020 18:59:24

US3462213

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		08 Nov 2020 14:07:54
Query 'Per DM CLR: Please note that there is no Con Savannah Peterson Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no meds taken diet controlled' (Site from DM).	(b) (4) (b) (4)	06 Nov 2020 01:03:25
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 16:11:05
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 22:42:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 22:42:48
Data point term sent to Coder	System	03 Oct 2020 19:00:10
User entered 'DIABETES II (DIET CONTROLLED)'	(b) (4), (b) (6)	03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Apr 2009'		03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 18:59:55



**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Apr 2009'	System	03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2009'	System	03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:59:55

**US3462213**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 18:59:55

US3462213

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Thyroid hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:12:50
Data point term sent to Coder	System	03 Oct 2020 19:01:11
User entered 'HYPERPLASTIC THYROID NODULE'	(b) (4), (b) (6)	03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Jan 2012'		03 Oct 2020 19:00:23



**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2012'	System	03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2012'	System	03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:23

**US3462213**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:23



US3462213

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:01:45
Data point term sent to Coder	System	03 Oct 2020 19:01:11
User entered 'OCCASIONAL BACK PAIN'	(b) (4), (b) (6)	03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1989'		03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1989'	System	03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1989'	System	03 Oct 2020 19:00:40



**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:40

**US3462213**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:40

US3462213

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
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) (b) (4)	03 Oct 2020 19:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:01:45
Data point term sent to Coder	System	03 Oct 2020 19:01:11
User entered 'OSTEOPOROSIS'	(b) (4), (b) (6)	03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2008'		03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:00:54



**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2008'	System	03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2008'	System	03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:54

**US3462213**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:00:54

US3462213

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
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) (b) (4)	03 Oct 2020 19:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:02:45
Data point term sent to Coder	System	03 Oct 2020 19:02:14
User entered 'DEGENERATIVE DISC DISEASE'	(b) (4), (b) (6)	03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Oct 2007'		03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:01:21



**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Oct 2007'	System	03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2007'	System	03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:21

**US3462213**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:21

US3462213

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
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 protrusion, LLT: Intervertebral disc bulging - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:18:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:18:36
Data point term sent to Coder	System	03 Oct 2020 19:02:12
User entered 'LUMBAR DISC BULGE'	(b) (4), (b) (6)	03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2008'		03 Oct 2020 19:01:43



**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2008'	System	03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2008'	System	03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:43

**US3462213**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:43



US3462213

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:02:45
Data point term sent to Coder	System	03 Oct 2020 19:02:14
User entered 'ANXIETY'	(b) (4), (b) (6)	03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1994'		03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1994'	System	03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1994'	System	03 Oct 2020 19:01:56



**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:56

**US3462213**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:01:56

US3462213

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
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) (b) (4)	03 Oct 2020 19:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:04:45
Data point term sent to Coder	System	03 Oct 2020 19:03:15
User entered 'DEPRESSION'	(b) (4), (b) (6)	03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2003'		03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2007'		03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:14



**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2003'	System	03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2003'	System	03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2007'	System	03 Oct 2020 19:02:14

**US3462213**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2007'	System	03 Oct 2020 19:02:14

US3462213

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:21:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 20:21:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 19:04:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 19:04:46
Data point term sent to Coder	System	03 Oct 2020 19:03:14
User entered 'SULFA ALLERGY (HIVES)'	(b) (4), (b) (6)	03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1987'		03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:02:31



**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1987'	System	03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1987'	System	03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:02:31

**US3462213**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:02:31

US3462213

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Iodine allergy, LLT: Iodine allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:16:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:16:37
Data point term sent to Coder	System	03 Oct 2020 19:03:14
User entered 'INJECTED IODINE ALLERGY'	(b) (4), (b) (6)	03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1986'		03 Oct 2020 19:02:50



**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1986'	System	03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1986'	System	03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:02:50

**US3462213**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:02:50



US3462213

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:04:45
Data point term sent to Coder	System	03 Oct 2020 19:03:15
User entered 'IRRITABLE BOWEL SYNDROME'	(b) (4), (b) (6)	03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2007'		03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2007'	System	03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2007'	System	03 Oct 2020 19:03:10



**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:03:10

**US3462213**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:03:10

US3462213

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:05:46
Data point term sent to Coder	System	03 Oct 2020 19:04:16
User entered 'LEFT KNEE PAIN'	(b) (4), (b) (6)	03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2012'		03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'Yes (Y)'		03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered empty.		03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:03:28



**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2012'	System	03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2012'	System	03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:03:28

**US3462213**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	03 Oct 2020 19:03:28

US3462213

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms benign, HLT: Gastrointestinal neoplasms benign NEC, PT: Benign abdominal neoplasm, LLT: Benign abdominal neoplasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 22:40:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 22:40:48
Data point term sent to Coder	System	03 Oct 2020 19:04:16
User entered 'BENIGN FATTY ABDOMINAL TUMOR'	(b) (4), (b) (6)	03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2010'		03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:04:04



**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2012'		03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2010'	System	03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2012'	System	03 Oct 2020 19:04:04

**US3462213**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2012'	System	03 Oct 2020 19:04:04

US3462213

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 19:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 19:05:46
Data point term sent to Coder	System	03 Oct 2020 19:05:17
User entered 'RIGHT BREAST LUMPECTOMY'	(b) (4), (b) (6)	03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Oct 2019'		03 Oct 2020 19:04:29



**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Oct 2019'		03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Oct 2019'	System	03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2019'	System	03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Oct 2019'	System	03 Oct 2020 19:04:29

**US3462213**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2019'	System	03 Oct 2020 19:04:29



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Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Lipoma excision, LLT: Lipoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:19:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:19:06
Data point term sent to Coder	System	03 Oct 2020 19:05:17
User entered 'ABDOMINIAL FATTY TUMOR REMOVED'	(b) (4), (b) (6)	03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2012'		03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 2012'		03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2012'	System	03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2012'	System	03 Oct 2020 19:05:09



**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2012'	System	03 Oct 2020 19:05:09

**US3462213**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2012'	System	03 Oct 2020 19:05:09

US3462213

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:06:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:06:47
Data point term sent to Coder	System	03 Oct 2020 19:06:17
User entered 'APPENDECTOMY'	(b) (4), (b) (6)	03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1986'		03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN UNK 1986'		03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:26



**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1986'	System	03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1986'	System	03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1986'	System	03 Oct 2020 19:05:26

**US3462213**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1986'	System	03 Oct 2020 19:05:26

US3462213

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:06:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:06:47
Data point term sent to Coder	System	03 Oct 2020 19:06:19
User entered 'CHOLECYSTECTOMY'	(b) (4), (b) (6)	03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Dec 2010'		03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'		03 Oct 2020 19:05:54



**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'UN Dec 2010'		03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'		03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	03 Oct 2020 19:05:54

**US3462213**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	03 Oct 2020 19:05:54

US3462213

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 01:03:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 01:03:25
Data point term sent to Coder	System	06 Nov 2020 01:02:07
User entered 'post menopausal'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un Dec 2010'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08



**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un Dec 2010'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	06 Nov 2020 01:01:08

**US3462213**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	06 Nov 2020 01:01:08



US3462213

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 01:03:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 01:03:25
Data point term sent to Coder	System	06 Nov 2020 01:02:07
User entered 'hysterectomy'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

US3462213

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:42:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un Dec 2010'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un Dec 2010'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	06 Nov 2020 01:01:54



**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Dec 2010'	System	06 Nov 2020 01:01:54

**US3462213**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2010'	System	06 Nov 2020 01:01:54

US3462213

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 01:04:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 01:04:25
Data point term sent to Coder	System	06 Nov 2020 01:03:07
User entered 'tubal ligation'	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un UNK 1998'	Savannah Peterson (b) (4)	06 Nov 2020 01:02:27

US3462213

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'No (N)'	Savannah Peterson (b) (4)	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered 'un UNK 1998'	Savannah Peterson (b) (4)	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:53:48
User entered '0'	Savannah Peterson (b) (4)	06 Nov 2020 01:02:27



**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1998'	System	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1998'	System	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1998'	System	06 Nov 2020 01:02:27

**US3462213**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1998'	System	06 Nov 2020 01:02:27

US3462213

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 17:42:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:44:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 17:44:04
Data point term sent to Coder	System	21 Jan 2021 17:42:48
User entered 'PERENNIAL ALLERGIC RHINITIS'	(b) (4), (b) (6)	21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User entered 'un UNK 1998'		21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User entered '0'		21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User entered 'Yes (Y)'		21 Jan 2021 17:42:42



**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User entered empty.		21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:46:33
User entered '0'		21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 1998'	System	21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '1998'	System	21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	21 Jan 2021 17:42:42

**US3462213**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	21 Jan 2021 17:42:42

US3462213

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 17:42:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 21:41:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 21:41:30
Data point term sent to Coder	System	29 Mar 2021 21:39:58
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:47



**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
DataPoint Verified.		30 Mar 2021 20:52:36
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'Jan 2015'	System	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '2015'	System	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	29 Mar 2021 21:39:47

**US3462213**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 17:42:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered empty.	System	29 Mar 2021 21:39:47



**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered 'Yes (Y)'		03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered '17 Aug 2020'		03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered '14:04'		03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '17 Aug 2020 14:04'	System	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered '148' cm		03 Oct 2020 19:07:23
DataPoint set to visible.	System	17 Aug 2020 22:13:10

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered '67.8' kg		03 Oct 2020 19:07:23
DataPoint set to visible.	System	17 Aug 2020 22:13:10

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered '30.95325'	System	03 Oct 2020 19:07:23
DataPoint set to visible.	System	17 Aug 2020 22:13:10

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'kg/m2'	System	03 Oct 2020 19:07:23
DataPoint set to visible.	System	17 Aug 2020 22:13:10



US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please delete current entries for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP and enter 'Not Done' in the data field of the eCRF for each result.' (Site from DM).		10 Nov 2020 21:06:55
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please delete current entries for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP and enter 'Not Done' in the data field of the eCRF for each result.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4)	06 Nov 2020 01:04:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Nov 2020 01:04:24
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please delete current entries for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP and enter 'Not Done' in the data field of the eCRF for each result.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:22:04
User entered '97.8' F		03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered empty; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:04:24
User entered 'Other (Other)'	(b) (4), (b) (6)	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered empty; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:04:24
User entered 'TYMPANIC'	(b) (4), (b) (6)	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:04:24
User entered '77'	(b) (4), (b) (6)	03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'bpm'	System	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:04:24
User entered '16'	(b) (4), (b) (6)	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'breaths/min'	System	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:04:24
User entered '132'	(b) (4), (b) (6)	03 Oct 2020 19:07:23



US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'mmHg'	System	03 Oct 2020 19:07:23

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:58:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:04:24
User entered '70'	(b) (4), (b) (6)	03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User entered 'mmHg'	System	03 Oct 2020 19:07:23

**US3462213**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39

US3462213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39

US3462213

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:12
User entered 'Yes (Y)'		03 Oct 2020 19:07:36

US3462213

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:12
User entered '17 Aug 2020'		03 Oct 2020 19:07:36

**US3462213**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:42:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered '17 Aug 2020'		03 Oct 2020 19:08:12



**US3462213**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:42:58**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered 'No (N)'		03 Oct 2020 19:08:12

US3462213

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).		18 Nov 2020 05:32:36
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:00:25
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 18:48:06
User entered 'Surgically sterile (SURGICALLY STERILE)'		03 Oct 2020 19:08:12

**US3462213**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:42:58**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered empty.		03 Oct 2020 19:08:12

US3462213

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:58

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered 'UN UNK 1998'		03 Oct 2020 19:08:12

US3462213

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:58

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered '0'		03 Oct 2020 19:08:12

US3462213

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:42:58

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered empty.		03 Oct 2020 19:08:12

**US3462213**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:42:58**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:44
User entered '0'		03 Oct 2020 19:08:12

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54



US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54



US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered 'No (N)'		03 Oct 2020 19:08:54

**US3462213**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:42:58**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered empty.		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
User entered 'I'	(b) (4), (b) (6)	03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered '0'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered '0'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered '0'		03 Oct 2020 19:08:54



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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered '0'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered '0'		03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
User entered '0'	(b) (4), (b) (6)	03 Oct 2020 19:08:54

US3462213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:30:39
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:58:52
User entered empty.		03 Oct 2020 19:08:54

US3462213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:02
User entered 'Yes (Y)'		04 Oct 2020 18:42:15

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:02
User entered '17 Aug 2020'		04 Oct 2020 18:42:15

US3462213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:02
User entered 'Clinic (Clinic)' reason for change: Data Entry Error		04 Oct 2020 18:42:32
User entered 'Home (Home)'		04 Oct 2020 18:42:15

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'VISIT1'	System	04 Oct 2020 18:42:15



US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:26

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:09:51
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:09:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 21:44:26
User entered '186699' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:26

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 21:44:26

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).		20 Oct 2020 15:02:45
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'confirmed answer' (Site from DM).		04 Oct 2020 18:44:01
User entered 'No (N)'		04 Oct 2020 18:43:45
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).		01 Sep 2020 14:23:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered 'No (N)'		04 Oct 2020 18:43:45

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered 'No (N)'		04 Oct 2020 18:43:45

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User closed query 'Please clarify response. Per Medical Hx, subject does have current Type II Diabetes (Diet Controlled). ' (Site from CRA). DataPoint Verified.		02 Apr 2021 18:34:32
		02 Apr 2021 18:33:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
Query 'Please clarify response. Per Medical Hx, subject does have current Type II Diabetes (Diet Controlled). ' answered with 'Corrected.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:25:40
DataPoint Un-verified.		10 Feb 2021 23:25:32
User entered 'Yes (Y)' reason for change: Data Entry Error		10 Feb 2021 23:25:32
User opened query 'Please clarify response. Per Medical Hx, subject does have current Type II Diabetes (Diet Controlled). ' (Site from CRA). DataPoint Verified.		03 Dec 2020 20:34:48
		03 Dec 2020 19:59:23
User entered 'No (N)'		04 Oct 2020 18:43:45

US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered 'No (N)'		04 Oct 2020 18:43:45



US3462213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:59:23
User entered 'No (N)'		04 Oct 2020 18:43:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:45:06

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).		10 Nov 2020 21:07:06
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:14
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:16:44
User entered '148' cm		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:05:14
User entered '67.8' kg	(b) (4), (b) (6)	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).		10 Nov 2020 21:07:06
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:14
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:16:44
User entered '148' cm		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:05:14
User entered '67.8' kg	(b) (4), (b) (6)	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Pre-Dose (PREDOSE)'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'Yes (Y)'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '17 Aug 2020'		04 Oct 2020 18:49:20



US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '14:04'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '17 Aug 2020 14:04'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '97.8' F		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'Other (Other)'		04 Oct 2020 18:49:20

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:42:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'TYMPANIC'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '77'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'bpm'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '16'		04 Oct 2020 18:49:20



US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'breaths/min'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '132'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '70'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).		10 Nov 2020 21:07:06
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:05:14
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter Not Done in the data field of the eCRF for Height and Weight at this visit.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:16:44
User entered '148' cm		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Savannah Peterson (b) (4)	06 Nov 2020 01:05:14
User entered '67.8' kg	(b) (4), (b) (6)	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Post-Dose (POSTDOSE)'		04 Oct 2020 18:49:20



US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'Yes (Y)'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '17 Aug 2020'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '15:35'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '17 Aug 2020 15:35'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '98.0' F		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'Other (Other)'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered 'TYMPANIC'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '79'		04 Oct 2020 18:49:20



US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'bpm'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '15'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'breaths/min'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '132'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:00:02
User entered '70'		04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 18:49:20

US3462213

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		30 Mar 2021 20:54:07
User closed query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' (Site from CRA).		30 Mar 2021 20:54:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
Query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' answered with 'Corrected.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:57:18
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	10 Feb 2021 23:57:12
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	10 Feb 2021 23:57:04
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 23:57:04
User entered 'No (N)' reason for change: Data Entry Error		10 Feb 2021 23:57:04
DataPoint Verified.		03 Dec 2020 20:00:29
User opened query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' (Site from CRA).		03 Dec 2020 20:00:26
User entered 'Yes (Y)'		04 Oct 2020 18:49:36



US3462213

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		30 Mar 2021 20:54:25
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:57:12
User entered empty; reason for change Data Entry Error		10 Feb 2021 23:57:12
DataPoint Verified.		03 Dec 2020 20:00:29
User entered '17 Aug 2020'		04 Oct 2020 18:49:36

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:17
User closed query 'Per CDM: Please complete the rest of the pages at this visit.' (Site from DM).	(b) (4)	16 Nov 2020 15:55:14
Query 'Per CDM: Please complete the rest of the pages at this visit.' answered with 'completed' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:04:52
User opened query 'Per CDM: Please complete the rest of the pages at this visit.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:14:34
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:01:17
User entered empty.	Savannah Peterson (b) (4)	17 Aug 2020 22:13:57

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:01:17
User entered empty.	Savannah Peterson (b) (4)	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:01:17
User entered '17 Aug 2020'	Savannah Peterson (b) (4)	17 Aug 2020 22:13:57

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:01:17
User entered '14:57'	Savannah Peterson (b) (4)	17 Aug 2020 22:13:57

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:42:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '17 Aug 2020 14:57'	System	17 Aug 2020 22:13:57



US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:17
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4) (b) (4)	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		03 Dec 2020 20:01:17
User entered 'ONCE'	System	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 22:13:57

US3462213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:31
User entered 'Yes (Y)'		04 Oct 2020 18:50:00

US3462213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:31
User entered '17 Aug 2020'		04 Oct 2020 18:50:00

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:31
User entered '14:30'		04 Oct 2020 18:50:00

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '17 Aug 2020 14:30'	System	04 Oct 2020 18:50:00

US3462213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:45
User entered '17 Aug 2020'		04 Oct 2020 18:50:22



**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Oct 2020 18:50:22

US3462213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:45
User entered 'Yes (Y)'		04 Oct 2020 18:50:22

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:45
User entered '14:32'		04 Oct 2020 18:50:22

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '17 Aug 2020 14:32'	System	04 Oct 2020 18:50:22

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Oct 2020 18:50:22

US3462213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:45
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:35:15
User entered 'Yes (Y)'		04 Oct 2020 18:50:22

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:01:45
User entered empty; reason for change Data Entry Error		11 Oct 2020 19:35:15
User entered '14:32'		04 Oct 2020 18:50:22

**US3462213**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	11 Oct 2020 19:35:15
User entered '17 Aug 2020 14:32'	System	04 Oct 2020 18:50:22



US3462213

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:00
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:27:54

US3462213

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	30 Sep 2020 19:27:54

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:38:16', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e8baee2b-37ca-4175-8a28-26c8ff08917e' User entered 'Yes (Y)'	System	17 Aug 2020 22:38:42
	System	17 Aug 2020 22:38:42

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:38:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e8baee2b-37ca-4175-8a28-26c8ff08917e' User entered '98.0'	System	17 Aug 2020 22:38:42
	System	17 Aug 2020 22:38:42

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:38:30', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e8baee2b-37ca-4175-8a28-26c8ff08917e'	System	17 Aug 2020 22:38:42
User entered 'No (N)'	System	17 Aug 2020 22:38:42

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:38:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e8baee2b-37ca-4175-8a28-26c8ff08917e'	System	17 Aug 2020 22:38:42
User entered '17 Aug 2020 15:38'	System	17 Aug 2020 22:38:42

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 15:17'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 17:47'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:50:57', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b'	System	18 Aug 2020 05:51:54
User entered 'Yes (Y)'	System	18 Aug 2020 05:51:54

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:51:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b' User entered '97.7'	System	18 Aug 2020 05:51:54
	System	18 Aug 2020 05:51:54

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:51:17', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b'	System	18 Aug 2020 05:51:54
User entered 'Yes (Y)'	System	18 Aug 2020 05:51:54

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
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 'per patient no pain med taken' (Site from System).	(b) (4)	16 Nov 2020 15:55:03
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).	Savannah Peterson (b) (4)	06 Nov 2020 00:56:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:51:42', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b'	(b) (4)	
User entered '1'	System	18 Aug 2020 05:51:54
	System	18 Aug 2020 05:51:54
	System	18 Aug 2020 05:51:54

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:51:42', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b' User entered '0'	System	18 Aug 2020 05:51:54
	System	18 Aug 2020 05:51:54

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:51:50', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '37c00c8b-b2bd-460f-b847-9a04e10ffe0b'	System	18 Aug 2020 05:51:54
User entered '17 Aug 2020 22:51'	System	18 Aug 2020 05:51:54



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 18:42'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 2'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:46:32', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6a375867-2c63-4903-a363-e3c069666779'	System	19 Aug 2020 06:47:00
User entered 'Yes (Y)'	System	19 Aug 2020 06:47:00

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:46:41', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6a375867-2c63-4903-a363-e3c069666779' User entered '96.8'	System	19 Aug 2020 06:47:00
	System	19 Aug 2020 06:47:00

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:46:52', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6a375867-2c63-4903-a363-e3c069666779'	System	19 Aug 2020 06:47:00
User entered 'No (N)'	System	19 Aug 2020 06:47:00

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:46:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6a375867-2c63-4903-a363-e3c069666779'	System	19 Aug 2020 06:47:00
User entered '18 Aug 2020 23:46'	System	19 Aug 2020 06:47:00

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 3'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:03:41', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '0ec338c4-d19b-4985-a23f-c66e96b6c4bf'	System	20 Aug 2020 07:05:03
User entered 'Yes (Y)'	System	20 Aug 2020 07:05:03

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:04:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '0ec338c4-d19b-4985-a23f-c66e96b6c4bf'	System	20 Aug 2020 07:05:03
User entered '97.5'	System	20 Aug 2020 07:05:03

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:04:57', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '0ec338c4-d19b-4985-a23f-c66e96b6c4bf'	System	20 Aug 2020 07:05:03
User entered 'No (N)'	System	20 Aug 2020 07:05:03

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:01', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '0ec338c4-d19b-4985-a23f-c66e96b6c4bf'	System	20 Aug 2020 07:05:03
User entered '20 Aug 2020 00:05'	System	20 Aug 2020 07:05:03

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 4'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 5'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:18', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b9064de-b62c-4b8d-aaa1-7b8eb8a88934' User entered 'Yes (Y)'	System	22 Aug 2020 06:07:33
	System	22 Aug 2020 06:07:33

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b9064de-b62c-4b8d-aaa1-7b8eb8a88934' User entered '97.5'	System	22 Aug 2020 06:07:33
	System	22 Aug 2020 06:07:33

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b9064de-b62c-4b8d-aaa1-7b8eb8a88934' User entered 'No (N)'	System	22 Aug 2020 06:07:33
	System	22 Aug 2020 06:07:33

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b9064de-b62c-4b8d-aaa1-7b8eb8a88934' User entered '21 Aug 2020 23:07'	System	22 Aug 2020 06:07:33
	System	22 Aug 2020 06:07:33

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 6'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a87013a-ee69-472c-b446-557c2bfdcd94'	System	23 Aug 2020 07:02:47
User entered 'Yes (Y)'	System	23 Aug 2020 07:02:47

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:37', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a87013a-ee69-472c-b446-557c2bfdcd94'	System	23 Aug 2020 07:02:47
User entered '97.0'	System	23 Aug 2020 07:02:47

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:41', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a87013a-ee69-472c-b446-557c2bfdcd94'	System	23 Aug 2020 07:02:47
User entered 'No (N)'	System	23 Aug 2020 07:02:47

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:43', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a87013a-ee69-472c-b446-557c2bfdcd94'	System	23 Aug 2020 07:02:47
User entered '23 Aug 2020 00:02'	System	23 Aug 2020 07:02:47

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 7'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:14', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f0339f4f-d1f8-4d86-9538-d2eb8ce327b3'	System	24 Aug 2020 16:17:30
User entered 'Yes (Y)'	System	24 Aug 2020 16:17:30

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:20', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f0339f4f-d1f8-4d86-9538-d2eb8ce327b3'	System	24 Aug 2020 16:17:30
User entered '97.5'	System	24 Aug 2020 16:17:30

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f0339f4f-d1f8-4d86-9538-d2eb8ce327b3'	System	24 Aug 2020 16:17:30
User entered 'No (N)'	System	24 Aug 2020 16:17:30

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:26', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f0339f4f-d1f8-4d86-9538-d2eb8ce327b3'	System	24 Aug 2020 16:17:30
User entered '24 Aug 2020 09:17'	System	24 Aug 2020 16:17:30

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:38:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c60f8d2a-0e24-49e0-8bd8-4fee2e641508'	System	17 Aug 2020 22:39:41
User entered 'None (1)'	System	17 Aug 2020 22:39:41



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c60f8d2a-0e24-49e0-8bd8-4fee2e641508'	System	17 Aug 2020 22:39:41
User entered 'No (N)'	System	17 Aug 2020 22:39:41

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:18', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c60f8d2a-0e24-49e0-8bd8-4fee2e641508'	System	17 Aug 2020 22:39:41
User entered 'No (N)'	System	17 Aug 2020 22:39:41

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:26', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c60f8d2a-0e24-49e0-8bd8-4fee2e641508'	System	17 Aug 2020 22:39:41
User entered 'None (1)'	System	17 Aug 2020 22:39:41

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:37', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c60f8d2a-0e24-49e0-8bd8-4fee2e641508'	System	17 Aug 2020 22:39:41
User entered '17 Aug 2020 15:39'	System	17 Aug 2020 22:39:41

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 15:17'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 17:47'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:04', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fec097f2-187f-429b-a848-e3532960a578'	System	18 Aug 2020 05:52:30
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 05:52:30



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fec097f2-187f-429b-a848-e3532960a578'	System	18 Aug 2020 05:52:30
User entered 'No (N)'	System	18 Aug 2020 05:52:30

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:15', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fec097f2-187f-429b-a848-e3532960a578'	System	18 Aug 2020 05:52:30
User entered 'No (N)'	System	18 Aug 2020 05:52:30

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:22', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fec097f2-187f-429b-a848-e3532960a578'	System	18 Aug 2020 05:52:30
User entered 'None (1)'	System	18 Aug 2020 05:52:30

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fec097f2-187f-429b-a848-e3532960a578'	System	18 Aug 2020 05:52:30
User entered '17 Aug 2020 22:52'	System	18 Aug 2020 05:52:30

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 18:42'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 2'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:47:06', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c90dad0c-141f-40db-abd2-e8efc000e3d3'	System	19 Aug 2020 06:47:57
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 06:47:57



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:47:35', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c90dad0c-141f-40db-abd2-e8efc000e3d3'	System	19 Aug 2020 06:47:57
User entered 'No (N)'	System	19 Aug 2020 06:47:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:47:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c90dad0c-141f-40db-abd2-e8efc000e3d3'	System	19 Aug 2020 06:47:57
User entered 'No (N)'	System	19 Aug 2020 06:47:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:47:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c90dad0c-141f-40db-abd2-e8efc000e3d3' User entered 'None (1)'	System	19 Aug 2020 06:47:57
	System	19 Aug 2020 06:47:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:47:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c90dad0c-141f-40db-abd2-e8efc000e3d3'	System	19 Aug 2020 06:47:57
User entered '18 Aug 2020 23:47'	System	19 Aug 2020 06:47:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 3'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5a1ad76b-3852-4d7b-b602-e20a2c7ca6e1' User entered 'None (1)'	System	20 Aug 2020 07:05:25
	System	20 Aug 2020 07:05:25



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5a1ad76b-3852-4d7b-b602-e20a2c7ca6e1' User entered 'No (N)'	System	20 Aug 2020 07:05:25
	System	20 Aug 2020 07:05:25

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:14', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5a1ad76b-3852-4d7b-b602-e20a2c7ca6e1' User entered 'No (N)'	System	20 Aug 2020 07:05:25
	System	20 Aug 2020 07:05:25

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:20', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5a1ad76b-3852-4d7b-b602-e20a2c7ca6e1' User entered 'None (1)'	System	20 Aug 2020 07:05:25
	System	20 Aug 2020 07:05:25

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:23', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5a1ad76b-3852-4d7b-b602-e20a2c7ca6e1' User entered '20 Aug 2020 00:05'	System	20 Aug 2020 07:05:25
	System	20 Aug 2020 07:05:25

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 4'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 5'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:37', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3c815dc3-a81b-41dc-aa58-b13860ed7c55' User entered 'None (1)'	System	22 Aug 2020 06:07:53
	System	22 Aug 2020 06:07:53

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3c815dc3-a81b-41dc-aa58-b13860ed7c55'	System	22 Aug 2020 06:07:53
User entered 'No (N)'	System	22 Aug 2020 06:07:53

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:42', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3c815dc3-a81b-41dc-aa58-b13860ed7c55'	System	22 Aug 2020 06:07:53
User entered 'No (N)'	System	22 Aug 2020 06:07:53

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:45', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3c815dc3-a81b-41dc-aa58-b13860ed7c55' User entered 'None (1)'	System	22 Aug 2020 06:07:53
	System	22 Aug 2020 06:07:53

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:49', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3c815dc3-a81b-41dc-aa58-b13860ed7c55'	System	22 Aug 2020 06:07:53
User entered '21 Aug 2020 23:07'	System	22 Aug 2020 06:07:53

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 6'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8075a9aa-e1b7-4aa4-a8d9-af9f8c46f008'	System	23 Aug 2020 07:03:01
User entered 'None (1)'	System	23 Aug 2020 07:03:01

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8075a9aa-e1b7-4aa4-a8d9-af9f8c46f008'	System	23 Aug 2020 07:03:01
User entered 'No (N)'	System	23 Aug 2020 07:03:01

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8075a9aa-e1b7-4aa4-a8d9-af9f8c46f008'	System	23 Aug 2020 07:03:01
User entered 'No (N)'	System	23 Aug 2020 07:03:01

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:55', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8075a9aa-e1b7-4aa4-a8d9-af9f8c46f008' User entered 'None (1)'	System	23 Aug 2020 07:03:01
	System	23 Aug 2020 07:03:01

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:02:58', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8075a9aa-e1b7-4aa4-a8d9-af9f8c46f008'	System	23 Aug 2020 07:03:01
User entered '23 Aug 2020 00:02'	System	23 Aug 2020 07:03:01

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 7'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:30', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '18388b9d-4f19-4342-a729-58337a2c2d08' User entered 'None (1)'	System	24 Aug 2020 16:17:43
	System	24 Aug 2020 16:17:43

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:33', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '18388b9d-4f19-4342-a729-58337a2c2d08'	System	24 Aug 2020 16:17:43
User entered 'No (N)'	System	24 Aug 2020 16:17:43

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:36', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '18388b9d-4f19-4342-a729-58337a2c2d08'	System	24 Aug 2020 16:17:43
User entered 'No (N)'	System	24 Aug 2020 16:17:43

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '18388b9d-4f19-4342-a729-58337a2c2d08' User entered 'None (1)'	System	24 Aug 2020 16:17:43
	System	24 Aug 2020 16:17:43

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '18388b9d-4f19-4342-a729-58337a2c2d08'	System	24 Aug 2020 16:17:43
User entered '24 Aug 2020 09:17'	System	24 Aug 2020 16:17:43

US3462213

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:39:57', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:40:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:40:03', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:40:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'None (0)'	System	17 Aug 2020 22:40:24

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:40:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered 'No (N)'	System	17 Aug 2020 22:40:24



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T15:40:21', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '67b04d92-f5bc-4b72-8a89-fd7759fbc289'	System	17 Aug 2020 22:40:24
User entered '17 Aug 2020 15:40'	System	17 Aug 2020 22:40:24

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 15:17'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 17:47'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:43', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:50', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:52:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'None (0)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:53:02', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered 'No (N)'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-17T22:53:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a0142581-1b06-43c7-81e2-5e294f0e9408'	System	18 Aug 2020 05:53:12
User entered '17 Aug 2020 22:53'	System	18 Aug 2020 05:53:12

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '17 Aug 2020 18:42'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 2'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'None (0)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d'	System	19 Aug 2020 06:48:35
User entered 'No interference with activity (1)'	System	19 Aug 2020 06:48:35

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:14', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'None (0)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:16', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'None (0)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:19', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'None (0)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:22', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'None (0)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d' User entered 'No (N)'	System	19 Aug 2020 06:48:35
	System	19 Aug 2020 06:48:35

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-18T23:48:32', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '773465df-f677-4ad0-b747-171db896bb9d'	System	19 Aug 2020 06:48:35
User entered '18 Aug 2020 23:48'	System	19 Aug 2020 06:48:35

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 3'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:26', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:33', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:36', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:41', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered 'None (0)'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:46', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541'	System	20 Aug 2020 07:05:50
User entered 'No (N)'	System	20 Aug 2020 07:05:50

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-20T00:05:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e34e7408-73c0-4d76-a08d-559a50ad7541' User entered '20 Aug 2020 00:05'	System	20 Aug 2020 07:05:50
	System	20 Aug 2020 07:05:50

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 4'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 5'	System	17 Aug 2020 22:13:57



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered 'None (0)'	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered 'None (0)'	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:07:59', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered 'None (0)'	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:08:02', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9' User entered 'None (0)'	System	22 Aug 2020 06:08:13
	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:08:04', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9' User entered 'None (0)'	System	22 Aug 2020 06:08:13
	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:08:06', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered 'None (0)'	System	22 Aug 2020 06:08:13

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:08:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered 'No (N)'	System	22 Aug 2020 06:08:13

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-21T23:08:11', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b9a5a9c8-97df-4056-985a-a2f30db9d4b9'	System	22 Aug 2020 06:08:13
User entered '21 Aug 2020 23:08'	System	22 Aug 2020 06:08:13



**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 6'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:03', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:11', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'None (0)'	System	23 Aug 2020 07:03:20

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:15', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered 'No (N)'	System	23 Aug 2020 07:03:20

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-23T00:03:18', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b025f885-1d05-4df4-a00e-7295e71c7863'	System	23 Aug 2020 07:03:20
User entered '23 Aug 2020 00:03'	System	23 Aug 2020 07:03:20

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 7'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:46', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8' User entered 'None (0)'	System	24 Aug 2020 16:18:04
	System	24 Aug 2020 16:18:04

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8'	System	24 Aug 2020 16:18:04
User entered 'None (0)'	System	24 Aug 2020 16:18:04



US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:50', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8' User entered 'None (0)'	System	24 Aug 2020 16:18:04
	System	24 Aug 2020 16:18:04

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:52', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8' User entered 'None (0)'	System	24 Aug 2020 16:18:04
	System	24 Aug 2020 16:18:04

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8'	System	24 Aug 2020 16:18:04
User entered 'None (0)'	System	24 Aug 2020 16:18:04

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8'	System	24 Aug 2020 16:18:04
User entered 'None (0)'	System	24 Aug 2020 16:18:04

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:17:59', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8'	System	24 Aug 2020 16:18:04
User entered 'No (N)'	System	24 Aug 2020 16:18:04

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-08-24T09:18:01', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b8b5484d-7bb1-4d78-8f3f-57fb5ca8abd8'	System	24 Aug 2020 16:18:04
User entered '24 Aug 2020 09:18'	System	24 Aug 2020 16:18:04

**US3462213**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:13:57

US3462213

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:24
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:23

**US3462213**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:24
User entered '24 Aug 2020'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:23

**US3462213**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:24
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:23

US3462213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:24
User entered empty.	Savannah Peterson (b) (4)	30 Sep 2020 19:28:23

US3462213

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:28
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:30

US3462213

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	30 Sep 2020 19:28:30

**US3462213**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:39
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:50

**US3462213**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:39
User entered '31 Aug 2020'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:50



**US3462213**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:39
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:50

US3462213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:39
User entered empty.	Savannah Peterson (b) (4)	30 Sep 2020 19:28:50

US3462213

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:43
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:28:56

**US3462213**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	30 Sep 2020 19:28:56

US3462213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:51
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:12

**US3462213**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:51
User entered '07 Sep 2020'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:12

**US3462213**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:51
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:12

US3462213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:51
User entered empty.	Savannah Peterson (b) (4)	30 Sep 2020 19:29:12



US3462213

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:02:55
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:15

**US3462213**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	30 Sep 2020 19:29:15

US3462213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User closed query 'Per source, subject reported an AE of 'Laryngitis' starting on 10Sep2020. Please add to EDC AE Log. ' (Site from CRA).		22 Feb 2021 06:35:55
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
Query 'Per source, subject reported an AE of 'Laryngitis' starting on 10Sep2020. Please add to EDC AE Log. ' answered with 'Added.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:07
DataPoint Verified.		03 Dec 2020 20:05:07
User opened query 'Per source, subject reported an AE of 'Laryngitis' starting on 10Sep2020. Please add to EDC AE Log. ' (Site from CRA).		03 Dec 2020 20:05:03
User entered 'Yes (Y)'		04 Oct 2020 18:56:38

US3462213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:05:07
User closed query 'Per CDM Re-query: Site response noted. However, site reports Date of Visit 2 (Study Visit Day 29) with -3/+7 Window Allowance per Schedule of Events on page 106 of Protocol Amendment 4, was completed on 30Sep2020, which is outside the Window Allowance for this visit. Please verify data and update Visit Date for Visit 2, else clarify why it has taken place outside the allowed window. Thank you.' (Site from DM).		18 Nov 2020 12:20:02
Query 'Per CDM Re-query: Site response noted. However, site reports Date of Visit 2 (Study Visit Day 29) with -3/+7 Window Allowance per Schedule of Events on page 106 of Protocol Amendment 4, was completed on 30Sep2020, which is outside the Window Allowance for this visit. Please verify data and update Visit Date for Visit 2, else clarify why it has taken place outside the allowed window. Thank you.' answered with 'patient received a flu vaccine and site waiting response from sponsor on how to proceed with v2' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:06:05
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 15:02:28
User opened query 'Per CDM Re-query: Site response noted. However, site reports Date of Visit 2 (Study Visit Day 29) with -3/+7 Window Allowance per Schedule of Events on page 106 of Protocol Amendment 4, was completed on 30Sep2020, which is outside the Window Allowance for this visit. Please verify data and update Visit Date for Visit 2, else clarify why it has taken place outside the allowed window. Thank you.' (Site from DM).		20 Oct 2020 15:02:25
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirmed' (Site from System).		04 Oct 2020 18:58:15

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	04 Oct 2020 18:56:38
User entered '30 Sep 2020'	(b) (4), (b) (6)	04 Oct 2020 18:56:38

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:05:07
User entered 'Clinic (Clinic)'		04 Oct 2020 18:56:38

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'VISIT2'	System	04 Oct 2020 18:56:38

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Pre-Dose (PREDOSE)'		04 Oct 2020 19:01:49



US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'Yes (Y)'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '30 Sep 2020'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '11:40'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '30 Sep 2020 11:40'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '97.8' F		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'Other (Other)'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'TYMPANIC'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '84'		04 Oct 2020 19:01:49



US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'bpm'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '14'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'breaths/min'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '124'		04 Oct 2020 19:01:49

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '74'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 19:01:49

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Post-Dose (POSTDOSE)'		04 Oct 2020 19:01:49



US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'Yes (Y)'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '30 Sep 2020'		04 Oct 2020 19:01:49

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '12:51'		04 Oct 2020 19:01:49

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '30 Sep 2020 12:51'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '97.8' F		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'Other (Other)'		04 Oct 2020 19:01:49

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:42:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered 'TYMPANIC'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '74'		04 Oct 2020 19:01:49



US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'bpm'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '14'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'breaths/min'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '128'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:07:19
User entered '86'		04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'mmHg'	System	04 Oct 2020 19:01:49

US3462213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		30 Mar 2021 20:57:08
User closed query 'Per source, a PE was completed at Visit 2 (30Sep2020). Please clarify. ' (Site from CRA).		30 Mar 2021 20:57:06
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
Query 'Per source, a PE was completed at Visit 2 (30Sep2020). Please clarify. ' answered with 'Corrected.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:57:51
DataPoint Un-verified.		10 Feb 2021 23:57:45
User entered 'Yes (Y)' reason for change: Data Entry Error		10 Feb 2021 23:57:45
DataPoint Verified.		03 Dec 2020 20:08:13
User opened query 'Per source, a PE was completed at Visit 2 (30Sep2020). Please clarify. ' (Site from CRA).		03 Dec 2020 20:08:11
User entered 'No (N)'		04 Oct 2020 19:01:58



US3462213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		30 Mar 2021 20:57:10
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:57:45
User entered '30 Sep 2020' reason for change: Data Entry Error		10 Feb 2021 23:57:45
DataPoint Verified.		03 Dec 2020 20:08:13
User entered empty.		04 Oct 2020 19:01:58

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered empty.	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered empty.	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered '30 Sep 2020'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:42:58**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered '12:14'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:42:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '30 Sep 2020 12:14'	System	30 Sep 2020 19:29:52



US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 20:08:30
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4)	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		03 Dec 2020 20:08:30
User entered 'ONCE'	System	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 19:29:52

US3462213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:42
User entered 'Yes (Y)'		04 Oct 2020 19:02:23

US3462213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:42
User entered '30 Sep 2020'		04 Oct 2020 19:02:23

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:42
User entered '12:10'		04 Oct 2020 19:02:23

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '30 Sep 2020 12:10'	System	04 Oct 2020 19:02:23

US3462213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:48
User entered '30 Sep 2020'		04 Oct 2020 19:02:48



**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Oct 2020 19:02:48

US3462213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:48
User entered 'Yes (Y)'		04 Oct 2020 19:02:48

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:48
User entered '12:12'		04 Oct 2020 19:02:48

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '30 Sep 2020 12:12'	System	04 Oct 2020 19:02:48

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Oct 2020 19:02:48

US3462213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:48
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:35:36
User entered 'Yes (Y)'		04 Oct 2020 19:02:48

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:48
User entered empty; reason for change Data Entry Error		11 Oct 2020 19:35:36
User entered '12:12'		04 Oct 2020 19:02:48

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	11 Oct 2020 19:35:36
User entered '30 Sep 2020 12:12'	System	04 Oct 2020 19:02:48



US3462213

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:08:55
User entered 'Yes (Y)'		04 Oct 2020 19:03:04

**US3462213**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	04 Oct 2020 19:03:04

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:53:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '03b36636-9820-4c33-8f02-6c8cbf809b97'	System	30 Sep 2020 19:53:59
User entered 'Yes (Y)'	System	30 Sep 2020 19:53:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:53:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '03b36636-9820-4c33-8f02-6c8cbf809b97'	System	30 Sep 2020 19:53:59
User entered '97.8'	System	30 Sep 2020 19:53:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:53:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '03b36636-9820-4c33-8f02-6c8cbf809b97'	System	30 Sep 2020 19:53:59
User entered 'No (N)'	System	30 Sep 2020 19:53:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:53:55', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '03b36636-9820-4c33-8f02-6c8cbf809b97'	System	30 Sep 2020 19:53:59
User entered '30 Sep 2020 12:53'	System	30 Sep 2020 19:53:59

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 12:34'	System	30 Sep 2020 19:29:52



**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:04'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:23:46', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36'	System	01 Oct 2020 06:24:16
User entered 'Yes (Y)'	System	01 Oct 2020 06:24:16

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:23:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36' User entered '98.0'	System	01 Oct 2020 06:24:16
	System	01 Oct 2020 06:24:16

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:01', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36'	System	01 Oct 2020 06:24:16
User entered 'Yes (Y)'	System	01 Oct 2020 06:24:16

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
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 'pt took aleve for injection site pain' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 12:22:13
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.' answered with 'pt took aleve for injection site pain' (Site from System).	Savannah Peterson (b) (4)	06 Nov 2020 00:59:46
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).	(b) (4)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36'	System	01 Oct 2020 06:24:16
User entered '1'	System	01 Oct 2020 06:24:16

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36' User entered '0'	System	01 Oct 2020 06:24:16
	System	01 Oct 2020 06:24:16

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '1a91ddd6-742b-4447-adc2-13e4b7a24f36'	System	01 Oct 2020 06:24:16
User entered '30 Sep 2020 23:24'	System	01 Oct 2020 06:24:16



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 2'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T22:59:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	System	02 Oct 2020 06:00:25
User entered 'Yes (Y)'	System	02 Oct 2020 06:00:25

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T22:59:58', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	System	02 Oct 2020 06:00:25
User entered '98.5'	System	02 Oct 2020 06:00:25

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:02', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	System	02 Oct 2020 06:00:25
User entered 'Yes (Y)'	System	02 Oct 2020 06:00:25

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
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 'pt took aleve for injection site pain' (Site from System).	(b) (4)	18 Nov 2020 12:22:20
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).	Savannah Peterson (b) (4)	06 Nov 2020 00:59:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	(b) (4)	
User entered '1'	System	02 Oct 2020 06:00:25
	System	02 Oct 2020 06:00:25
	System	02 Oct 2020 06:00:25

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	System	02 Oct 2020 06:00:25
User entered '0'	System	02 Oct 2020 06:00:25



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:20', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '116de341-c3e9-4e48-b210-9982a6bfbe75'	System	02 Oct 2020 06:00:25
User entered '01 Oct 2020 23:00'	System	02 Oct 2020 06:00:25

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 3'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 4'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 5'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:21', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8094bd69-eccb-4abe-8740-959d6415490c' User entered 'Yes (Y)'	System	05 Oct 2020 18:18:40
	System	05 Oct 2020 18:18:40

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:29', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8094bd69-eccb-4abe-8740-959d6415490c' User entered '97.6'	System	05 Oct 2020 18:18:40
	System	05 Oct 2020 18:18:40



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:33', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8094bd69-eccb-4abe-8740-959d6415490c' User entered 'No (N)'	System	05 Oct 2020 18:18:40
	System	05 Oct 2020 18:18:40

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:36', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '8094bd69-eccb-4abe-8740-959d6415490c'	System	05 Oct 2020 18:18:40
User entered '05 Oct 2020 11:18'	System	05 Oct 2020 18:18:40

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 6'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:30', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'efbd3ad3-e971-49da-993e-0435da182e6e' User entered 'Yes (Y)'	System	06 Oct 2020 05:10:53
	System	06 Oct 2020 05:10:53

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:41', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'efbd3ad3-e971-49da-993e-0435da182e6e' User entered '97.6'	System	06 Oct 2020 05:10:53
	System	06 Oct 2020 05:10:53

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:45', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'efbd3ad3-e971-49da-993e-0435da182e6e'	System	06 Oct 2020 05:10:53
User entered 'No (N)'	System	06 Oct 2020 05:10:53



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'efbd3ad3-e971-49da-993e-0435da182e6e'	System	06 Oct 2020 05:10:53
User entered '05 Oct 2020 22:10'	System	06 Oct 2020 05:10:53

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 7'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:11:29', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b0f9681f-b1d2-4155-9d65-01c382cc4df2'	System	07 Oct 2020 06:12:24
User entered 'Yes (Y)'	System	07 Oct 2020 06:12:24

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:11:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b0f9681f-b1d2-4155-9d65-01c382cc4df2'	System	07 Oct 2020 06:12:24
User entered '97.6'	System	07 Oct 2020 06:12:24

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:17', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b0f9681f-b1d2-4155-9d65-01c382cc4df2'	System	07 Oct 2020 06:12:24
User entered 'No (N)'	System	07 Oct 2020 06:12:24

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:22', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b0f9681f-b1d2-4155-9d65-01c382cc4df2'	System	07 Oct 2020 06:12:24
User entered '06 Oct 2020 23:12'	System	07 Oct 2020 06:12:24



US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:01', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c2f23379-ada2-4456-b7ba-f8f547bee3d7'	System	30 Sep 2020 19:54:26
User entered 'None (1)'	System	30 Sep 2020 19:54:26

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:04', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c2f23379-ada2-4456-b7ba-f8f547bee3d7'	System	30 Sep 2020 19:54:26
User entered 'No (N)'	System	30 Sep 2020 19:54:26

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:11', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c2f23379-ada2-4456-b7ba-f8f547bee3d7'	System	30 Sep 2020 19:54:26
User entered 'No (N)'	System	30 Sep 2020 19:54:26

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:19', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c2f23379-ada2-4456-b7ba-f8f547bee3d7'	System	30 Sep 2020 19:54:26
User entered 'None (1)'	System	30 Sep 2020 19:54:26

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:23', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'c2f23379-ada2-4456-b7ba-f8f547bee3d7'	System	30 Sep 2020 19:54:26
User entered '30 Sep 2020 12:54'	System	30 Sep 2020 19:54:26



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 12:34'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:04'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'dec66391-085c-4599-b632-cf6e37e84590'	System	01 Oct 2020 06:25:05
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 06:25:05

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'dec66391-085c-4599-b632-cf6e37e84590'	System	01 Oct 2020 06:25:05
User entered 'No (N)'	System	01 Oct 2020 06:25:05

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:46', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'dec66391-085c-4599-b632-cf6e37e84590'	System	01 Oct 2020 06:25:05
User entered 'No (N)'	System	01 Oct 2020 06:25:05

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:24:57', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'dec66391-085c-4599-b632-cf6e37e84590' User entered 'None (1)'	System	01 Oct 2020 06:25:05
	System	01 Oct 2020 06:25:05

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'dec66391-085c-4599-b632-cf6e37e84590'	System	01 Oct 2020 06:25:05
User entered '30 Sep 2020 23:25'	System	01 Oct 2020 06:25:05



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 2'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:42', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e45a0913-e438-4b07-bdcc-14ecca41fb53'	System	02 Oct 2020 06:00:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 06:00:57

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:45', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e45a0913-e438-4b07-bdcc-14ecca41fb53'	System	02 Oct 2020 06:00:57
User entered 'No (N)'	System	02 Oct 2020 06:00:57

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e45a0913-e438-4b07-bdcc-14ecca41fb53'	System	02 Oct 2020 06:00:57
User entered 'No (N)'	System	02 Oct 2020 06:00:57

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e45a0913-e438-4b07-bdcc-14ecca41fb53' User entered 'None (1)'	System	02 Oct 2020 06:00:57
	System	02 Oct 2020 06:00:57

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:00:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e45a0913-e438-4b07-bdcc-14ecca41fb53'	System	02 Oct 2020 06:00:57
User entered '01 Oct 2020 23:00'	System	02 Oct 2020 06:00:57



**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 3'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 4'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

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)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 5'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fe5d36d9-1dc9-4e5e-a991-4e6ef1dcfbe8'	System	05 Oct 2020 18:18:53
User entered 'None (1)'	System	05 Oct 2020 18:18:53



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:43', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fe5d36d9-1dc9-4e5e-a991-4e6ef1dcfbe8'	System	05 Oct 2020 18:18:53
User entered 'No (N)'	System	05 Oct 2020 18:18:53

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:45', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fe5d36d9-1dc9-4e5e-a991-4e6ef1dcfbe8'	System	05 Oct 2020 18:18:53
User entered 'No (N)'	System	05 Oct 2020 18:18:53

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fe5d36d9-1dc9-4e5e-a991-4e6ef1dcfbe8'	System	05 Oct 2020 18:18:53
User entered 'None (1)'	System	05 Oct 2020 18:18:53

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'fe5d36d9-1dc9-4e5e-a991-4e6ef1dcfbe8'	System	05 Oct 2020 18:18:53
User entered '05 Oct 2020 11:18'	System	05 Oct 2020 18:18:53

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 6'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79ae3652-460f-4084-8b57-a1117ba064b9' User entered 'None (1)'	System	06 Oct 2020 05:11:08
	System	06 Oct 2020 05:11:08



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79ae3652-460f-4084-8b57-a1117ba064b9' User entered 'No (N)'	System	06 Oct 2020 05:11:08
	System	06 Oct 2020 05:11:08

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:10:59', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79ae3652-460f-4084-8b57-a1117ba064b9' User entered 'No (N)'	System	06 Oct 2020 05:11:08
	System	06 Oct 2020 05:11:08

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:02', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79ae3652-460f-4084-8b57-a1117ba064b9' User entered 'None (1)'	System	06 Oct 2020 05:11:08
	System	06 Oct 2020 05:11:08

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79ae3652-460f-4084-8b57-a1117ba064b9' User entered '05 Oct 2020 22:11'	System	06 Oct 2020 05:11:08
	System	06 Oct 2020 05:11:08

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 7'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:39', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e9241ce9-5270-4f12-bf77-ba8c2fee230f' User entered 'None (1)'	System	07 Oct 2020 06:12:58
	System	07 Oct 2020 06:12:58



US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:45', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e9241ce9-5270-4f12-bf77-ba8c2fee230f' User entered 'No (N)'	System	07 Oct 2020 06:12:58
	System	07 Oct 2020 06:12:58

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:49', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e9241ce9-5270-4f12-bf77-ba8c2fee230f' User entered 'No (N)'	System	07 Oct 2020 06:12:58
	System	07 Oct 2020 06:12:58

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:52', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e9241ce9-5270-4f12-bf77-ba8c2fee230f' User entered 'None (1)'	System	07 Oct 2020 06:12:58
	System	07 Oct 2020 06:12:58

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:55', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e9241ce9-5270-4f12-bf77-ba8c2fee230f' User entered '06 Oct 2020 23:12'	System	07 Oct 2020 06:12:58
	System	07 Oct 2020 06:12:58

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:27', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:29', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:34', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:36', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4' User entered 'None (0)'	System	30 Sep 2020 19:55:20
	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:44', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4'	System	30 Sep 2020 19:55:20
User entered 'No (N)'	System	30 Sep 2020 19:55:20

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T12:54:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'd44a0fbe-f123-4e61-8ca9-5dacc3160ad4'	System	30 Sep 2020 19:55:20
User entered '30 Sep 2020 12:54'	System	30 Sep 2020 19:55:20

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 12:34'	System	30 Sep 2020 19:29:52



**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:04'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:11', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:15', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:19', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'None (0)'	System	01 Oct 2020 06:25:34



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:22', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered 'No (N)'	System	01 Oct 2020 06:25:34

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-09-30T23:25:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '82d2e37d-80dc-4607-8baf-e98794ce7f69'	System	01 Oct 2020 06:25:34
User entered '30 Sep 2020 23:25'	System	01 Oct 2020 06:25:34

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '30 Sep 2020 15:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 2'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286'	System	02 Oct 2020 06:01:41
User entered 'No interference with activity (1)'	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286' User entered 'None (0)'	System	02 Oct 2020 06:01:41
	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286' User entered 'None (0)'	System	02 Oct 2020 06:01:41
	System	02 Oct 2020 06:01:41



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286' User entered 'None (0)'	System	02 Oct 2020 06:01:41
	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:26', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286'	System	02 Oct 2020 06:01:41
User entered 'None (0)'	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286'	System	02 Oct 2020 06:01:41
User entered 'No interference with activity (1)'	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:35', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286'	System	02 Oct 2020 06:01:41
User entered 'No (N)'	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-01T23:01:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '000112cf-4dd5-475f-9893-240d898c6286'	System	02 Oct 2020 06:01:41
User entered '01 Oct 2020 23:01'	System	02 Oct 2020 06:01:41

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 3'	System	30 Sep 2020 19:29:52



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 4'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38



**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:42:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:42:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 5'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:18:59', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:02', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:04', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered 'None (0)'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3'	System	05 Oct 2020 18:19:43
User entered 'No (N)'	System	05 Oct 2020 18:19:43

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:42:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T11:19:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '59c90726-da26-4b85-8351-03e2393fadb3' User entered '05 Oct 2020 11:19'	System	05 Oct 2020 18:19:43
	System	05 Oct 2020 18:19:43

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 19:29:52



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 6'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c'	System	06 Oct 2020 05:11:44
User entered 'No interference with activity (1)'	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:14', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered 'None (0)'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:18', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered 'None (0)'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:27', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered 'None (0)'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:30', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered 'None (0)'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:33', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered 'None (0)'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:37', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c'	System	06 Oct 2020 05:11:44
User entered 'No (N)'	System	06 Oct 2020 05:11:44



**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-05T22:11:40', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '046387e7-82f6-459f-ad8a-0f8f6976ae1c' User entered '05 Oct 2020 22:11'	System	06 Oct 2020 05:11:44
	System	06 Oct 2020 05:11:44

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	30 Sep 2020 19:29:52
User entered 'Day 7'	System	30 Sep 2020 19:29:52

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:12:58', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'None (0)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'None (0)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:01', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e'	System	07 Oct 2020 06:13:14
User entered 'None (0)'	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:03', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'None (0)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14



US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'None (0)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'None (0)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered 'No (N)'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-06T23:13:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7020928d-dd1e-4bcf-a0e1-f81a0dfb817e' User entered '06 Oct 2020 23:13'	System	07 Oct 2020 06:13:14
	System	07 Oct 2020 06:13:14

US3462213

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:42:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:42:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 19:29:52

**US3462213**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:09:19
User entered 'Yes (Y)'		15 Oct 2020 22:11:23

US3462213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:09:19
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Oct 2020 22:11:44
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	15 Oct 2020 22:11:44
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 22:11:44
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Oct 2020 22:11:23
User entered '07 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 22:11:23



US3462213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:09:19
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 22:11:23

US3462213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:09:19
User entered empty.		15 Oct 2020 22:11:23

US3462213

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	03 Dec 2020 20:09:23
User entered 'Yes (Y)'		15 Oct 2020 22:11:53

**US3462213**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	15 Oct 2020 22:11:53

**US3462213**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:12:15
User entered 'No (N)'		25 Nov 2020 00:30:06

US3462213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:12:15
User entered empty.		25 Nov 2020 00:30:06

**US3462213**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:12:15
User entered empty.		25 Nov 2020 00:30:06

US3462213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
DataPoint Verified.		30 Mar 2021 20:44:10
User closed query 'Please document reason why contact was not attempted. ' (Site from CRA).		30 Mar 2021 20:43:24
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
Query 'Please document reason why contact was not attempted. ' answered with 'Entered.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 23:56:51
DataPoint Un-verified.		10 Feb 2021 23:56:45
User entered 'Due to Visit 2 occurring so late, Day 43 Phone Call and Visit 3 happened on the same date Patient was seen in office.' reason for change: Data Entry Error		10 Feb 2021 23:56:45
DataPoint Verified.		03 Dec 2020 20:12:15
User opened query 'Please document reason why contact was not attempted. ' (Site from CRA).		03 Dec 2020 20:12:12
User entered empty.		25 Nov 2020 00:30:06



US3462213

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:12:25
User entered 'Yes (Y)'		19 Oct 2020 19:48:45

**US3462213**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	19 Oct 2020 19:48:45

**US3462213**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:13:14
User entered 'No (N)'		25 Nov 2020 00:30:13

US3462213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:13:14
User entered empty.		25 Nov 2020 00:30:13

**US3462213**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:13:14
User entered empty.		25 Nov 2020 00:30:13

US3462213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User closed query 'Please document reason why contact was not attempted. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:47:13 30 Mar 2021 20:47:10
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
Query 'Please document reason why contact was not attempted. ' answered with 'Entered.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 23:59:33 10 Feb 2021 23:59:28
User entered 'Contact was missed due to confusion regarding late Visit 2.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 23:59:28 03 Dec 2020 20:13:14
User opened query 'Please document reason why contact was not attempted. ' (Site from CRA). User entered empty.	(b) (4), (b) (6)	03 Dec 2020 20:13:11 25 Nov 2020 00:30:13

**US3462213**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:13:21
User entered 'Yes (Y)'		19 Oct 2020 19:48:52

**US3462213**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	19 Oct 2020 19:48:52



US3462213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:34
User entered 'Yes (Y)'		19 Oct 2020 19:49:06

US3462213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:34
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		18 Nov 2020 12:21:03
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'site completed this visit on 10/14 to get patient back on to schedule' (Site from System).	Savannah Peterson (b) (4) (b) (4)	06 Nov 2020 01:06:46
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Oct 2020 19:49:06
User entered '14 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 19:49:06

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:34
User entered 'Clinic (Clinic)'		19 Oct 2020 19:49:06

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'VISIT3'	System	19 Oct 2020 19:49:06

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered 'No (N)'		19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	19 Oct 2020 19:49:11



US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11



**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:20:56
User entered empty.		19 Oct 2020 19:49:11

US3462213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered empty.	System	19 Oct 2020 19:49:11

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28

US3462213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Dec 2020 23:21:03
User entered 'No (N)'		19 Oct 2020 19:49:15

US3462213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Dec 2020 23:21:03
User entered empty.		19 Oct 2020 19:49:15

US3462213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:16
User entered 'Yes (Y)'		19 Oct 2020 19:49:28



US3462213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:16
User entered '14 Oct 2020'		19 Oct 2020 19:49:28

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:16
User entered '12:00'		19 Oct 2020 19:49:28

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered '14 Oct 2020 12:00'	System	19 Oct 2020 19:49:28

US3462213

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:24
User entered 'Yes (Y)'		19 Oct 2020 19:49:34

**US3462213**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	19 Oct 2020 19:49:34

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 64'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 71'	System	17 Aug 2020 22:13:57

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-27T22:07:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f3381b1e-f571-45dd-ba61-cbcd64e0cff2'	System	28 Oct 2020 05:07:27
User entered 'No (N)'	System	28 Oct 2020 05:07:27

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-27T22:07:19', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f3381b1e-f571-45dd-ba61-cbcd64e0cff2'	System	28 Oct 2020 05:07:27
User entered 'No (N)'	System	28 Oct 2020 05:07:27

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD1E8D00-23CD-4B88-A36E-1BA937538FEF)', Time: '2020-10-27T22:07:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'f3381b1e-f571-45dd-ba61-cbcd64e0cff2' User entered '27 Oct 2020 22:07:24'	System	28 Oct 2020 05:07:27
	System	28 Oct 2020 05:07:27

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 78'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:46:28
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered 'Day 92'	System	17 Aug 2020 22:13:57

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-16T17:51:48', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fb1fea9-479e-47ec-b8cb-047926cec4ee'	System	17 Nov 2020 01:52:04
User entered 'No (N)'	System	17 Nov 2020 01:52:04

US3462213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-16T17:51:54', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fb1fea9-479e-47ec-b8cb-047926cec4ee'	System	17 Nov 2020 01:52:04
User entered 'No (N)'	System	17 Nov 2020 01:52:04

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-16T17:52:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fb1fea9-479e-47ec-b8cb-047926cec4ee' User entered '16 Nov 2020 17:52:00'	System	17 Nov 2020 01:52:04
	System	17 Nov 2020 01:52:04

**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 22:13:57



**US3462213**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:24:38
Data entry locked.	System	17 Aug 2020 22:13:57
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 22:13:57

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-20T11:52:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b1513525-3d6d-439e-8e79-34f443ed271e' User entered 'No (N)'	System	20 Nov 2020 19:53:00
	System	20 Nov 2020 19:53:00

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-20T11:52:52', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b1513525-3d6d-439e-8e79-34f443ed271e'	System	20 Nov 2020 19:53:00
User entered 'No (N)'	System	20 Nov 2020 19:53:00

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-20T11:52:56', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b1513525-3d6d-439e-8e79-34f443ed271e' User entered '20 Nov 2020 11:52:56'	System	20 Nov 2020 19:53:00
	System	20 Nov 2020 19:53:00

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-25T17:35:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '025c9231-e49a-413b-8dd3-7d1619679224' User entered 'No (N)'	System	26 Nov 2020 01:35:16
	System	26 Nov 2020 01:35:16

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-25T17:35:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '025c9231-e49a-413b-8dd3-7d1619679224' User entered 'No (N)'	System	26 Nov 2020 01:35:16

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-11-25T17:35:13', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '025c9231-e49a-413b-8dd3-7d1619679224'	System	26 Nov 2020 01:35:16
User entered '25 Nov 2020 17:35:13'	System	26 Nov 2020 01:35:16

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-02T00:04:32', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b048813-8e0a-466d-97f0-61d78660cc5d' User entered 'No (N)'	System	02 Dec 2020 08:04:40
	System	02 Dec 2020 08:04:40

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-02T00:04:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b048813-8e0a-466d-97f0-61d78660cc5d'	System	02 Dec 2020 08:04:40
User entered 'No (N)'	System	02 Dec 2020 08:04:40



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-02T00:04:36', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '6b048813-8e0a-466d-97f0-61d78660cc5d' User entered '02 Dec 2020 00:04:36'	System	02 Dec 2020 08:04:40
	System	02 Dec 2020 08:04:40

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-09T19:36:08', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04fc5112-b7cf-4244-83f3-150b9e9b62f8' User entered 'No (N)'	System	10 Dec 2020 03:36:26
	System	10 Dec 2020 03:36:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-09T19:36:16', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04fc5112-b7cf-4244-83f3-150b9e9b62f8' User entered 'No (N)'	System	10 Dec 2020 03:36:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-09T19:36:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04fc5112-b7cf-4244-83f3-150b9e9b62f8' User entered '09 Dec 2020 19:36:24'	System	10 Dec 2020 03:36:26
	System	10 Dec 2020 03:36:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:51:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1' User entered 'Yes (Y)'	System	17 Dec 2020 02:52:36
	System	17 Dec 2020 02:52:36

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:51:46', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1' User entered 'No (N)'	System	17 Dec 2020 02:52:36
	System	17 Dec 2020 02:52:36

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:51:55', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1' User entered 'No (N)'	System	17 Dec 2020 02:52:36
	System	17 Dec 2020 02:52:36

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:52:06', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1' User entered 'Yes (Y)'	System	17 Dec 2020 02:52:36
	System	17 Dec 2020 02:52:36

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:52:15', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1'	System	17 Dec 2020 02:52:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 02:52:36

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-16T18:52:25', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '7572ec87-86be-471e-a037-23e49f92b9b1' User entered '16 Dec 2020 18:52:25'	System	17 Dec 2020 02:52:36
	System	17 Dec 2020 02:52:36



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-23T14:27:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '199cfd04-4165-4f2d-bf0e-0597c30b570e' User entered 'No (N)'	System	23 Dec 2020 22:27:22
	System	23 Dec 2020 22:27:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-23T14:27:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '199cfd04-4165-4f2d-bf0e-0597c30b570e' User entered 'No (N)'	System	23 Dec 2020 22:27:22
	System	23 Dec 2020 22:27:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-23T14:27:16', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '199cfd04-4165-4f2d-bf0e-0597c30b570e' User entered '23 Dec 2020 14:27:16'	System	23 Dec 2020 22:27:22
	System	23 Dec 2020 22:27:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-30T00:02:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '83acbc07-7ea7-4df7-af33-323452b10156'	System	30 Dec 2020 08:02:30
User entered 'No (N)'	System	30 Dec 2020 08:02:30

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-30T00:02:23', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '83acbc07-7ea7-4df7-af33-323452b10156' User entered 'No (N)'	System	30 Dec 2020 08:02:30
	System	30 Dec 2020 08:02:30

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2020-12-30T00:02:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '83acbc07-7ea7-4df7-af33-323452b10156' User entered '30 Dec 2020 00:02:28'	System	30 Dec 2020 08:02:30
	System	30 Dec 2020 08:02:30

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:25:53', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce' User entered 'Yes (Y)'	System	06 Jan 2021 18:26:41
	System	06 Jan 2021 18:26:41



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:26:03', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce'	System	06 Jan 2021 18:26:41
User entered 'No (N)'	System	06 Jan 2021 18:26:41

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:26:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce' User entered 'No (N)'	System	06 Jan 2021 18:26:41
	System	06 Jan 2021 18:26:41

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:26:16', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce' User entered 'Yes (Y)'	System	06 Jan 2021 18:26:41
	System	06 Jan 2021 18:26:41

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:26:24', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce'	System	06 Jan 2021 18:26:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 18:26:41

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-06T10:26:28', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '79eb242d-9a3c-4b3e-a316-9c3de09cd7ce' User entered '06 Jan 2021 10:26:28'	System	06 Jan 2021 18:26:41
	System	06 Jan 2021 18:26:41

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-16T11:40:30', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '46654e33-d386-4933-b99c-490f3d1290ff' User entered 'No (N)'	System	16 Jan 2021 19:40:42
	System	16 Jan 2021 19:40:42

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-16T11:40:34', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '46654e33-d386-4933-b99c-490f3d1290ff' User entered 'No (N)'	System	16 Jan 2021 19:40:42
	System	16 Jan 2021 19:40:42

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-16T11:40:38', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '46654e33-d386-4933-b99c-490f3d1290ff' User entered '16 Jan 2021 11:40:38'	System	16 Jan 2021 19:40:42
	System	16 Jan 2021 19:40:42

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-20T08:24:03', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5d233945-329d-451e-a019-c5e5b2c8558b'	System	20 Jan 2021 16:24:15
User entered 'No (N)'	System	20 Jan 2021 16:24:15

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-20T08:24:07', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5d233945-329d-451e-a019-c5e5b2c8558b'	System	20 Jan 2021 16:24:15
User entered 'No (N)'	System	20 Jan 2021 16:24:15



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-20T08:24:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '5d233945-329d-451e-a019-c5e5b2c8558b' User entered '20 Jan 2021 08:24:10'	System	20 Jan 2021 16:24:15
	System	20 Jan 2021 16:24:15

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-27T11:47:04', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '16303a1a-f213-44af-be14-bb9dfc964b9e' User entered 'No (N)'	System	27 Jan 2021 19:48:19
	System	27 Jan 2021 19:48:19

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-27T11:47:43', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '16303a1a-f213-44af-be14-bb9dfc964b9e' User entered 'Yes (Y)'	System	27 Jan 2021 19:48:19
	System	27 Jan 2021 19:48:19

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-27T11:47:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '16303a1a-f213-44af-be14-bb9dfc964b9e'	System	27 Jan 2021 19:48:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 19:48:19

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-01-27T11:48:10', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '16303a1a-f213-44af-be14-bb9dfc964b9e' User entered '27 Jan 2021 11:48:10'	System	27 Jan 2021 19:48:19
	System	27 Jan 2021 19:48:19



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-03T18:46:31', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e4f8bc6d-814a-4c75-afab-a3d0a2fd7b04'	System	04 Feb 2021 02:47:08
User entered 'No (N)'	System	04 Feb 2021 02:47:08

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-03T18:46:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e4f8bc6d-814a-4c75-afab-a3d0a2fd7b04' User entered 'No (N)'	System	04 Feb 2021 02:47:08
	System	04 Feb 2021 02:47:08

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-03T18:46:52', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'e4f8bc6d-814a-4c75-afab-a3d0a2fd7b04'	System	04 Feb 2021 02:47:08
User entered '03 Feb 2021 18:46:52'	System	04 Feb 2021 02:47:08

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-13T18:48:44', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a658f8eb-fbbb-4998-b366-b97415c3b4e2' User entered 'No (N)'	System	14 Feb 2021 02:48:54

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-13T18:48:47', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a658f8eb-fbbb-4998-b366-b97415c3b4e2' User entered 'No (N)'	System	14 Feb 2021 02:48:54

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-13T18:48:51', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'a658f8eb-fbbb-4998-b366-b97415c3b4e2'	System	14 Feb 2021 02:48:54
User entered '13 Feb 2021 18:48:51'	System	14 Feb 2021 02:48:54

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-17T15:51:05', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '91c4e193-f660-4ece-ad9e-d19783d57624' User entered 'No (N)'	System	17 Feb 2021 23:51:17
	System	17 Feb 2021 23:51:17



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-17T15:51:09', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '91c4e193-f660-4ece-ad9e-d19783d57624' User entered 'No (N)'	System	17 Feb 2021 23:51:17
	System	17 Feb 2021 23:51:17

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-17T15:51:12', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '91c4e193-f660-4ece-ad9e-d19783d57624' User entered '17 Feb 2021 15:51:12'	System	17 Feb 2021 23:51:17
	System	17 Feb 2021 23:51:17

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-26T12:00:24-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '85570fcd-1cb7-426b-b91f-8b0990560d60' User entered 'No (N)'	System	26 Feb 2021 20:00:51
	System	26 Feb 2021 20:00:51

US3462213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-26T12:00:28-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '85570fcd-1cb7-426b-b91f-8b0990560d60' User entered 'No (N)'	System	26 Feb 2021 20:00:51
	System	26 Feb 2021 20:00:51

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-02-26T12:00:32-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '85570fcd-1cb7-426b-b91f-8b0990560d60' User entered '26 Feb 2021 20:00:32'	System	26 Feb 2021 20:00:51
	System	26 Feb 2021 20:00:51



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-04T09:10:14-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '9579a8d9-9a0a-4d9a-b810-c984228c76e1' User entered 'No (N)'	System	04 Mar 2021 17:15:37
	System	04 Mar 2021 17:15:37

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-04T09:10:18-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '9579a8d9-9a0a-4d9a-b810-c984228c76e1'	System	04 Mar 2021 17:15:37
User entered 'No (N)'	System	04 Mar 2021 17:15:37

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-04T09:10:22-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '9579a8d9-9a0a-4d9a-b810-c984228c76e1' User entered '04 Mar 2021 09:10:22'	System	04 Mar 2021 17:15:37
	System	04 Mar 2021 17:15:37

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-11T17:22:07-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b2e22366-9b0f-4ad4-af46-b042661358ac'	System	12 Mar 2021 01:22:22
User entered 'No (N)'	System	12 Mar 2021 01:22:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-11T17:22:13-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b2e22366-9b0f-4ad4-af46-b042661358ac'	System	12 Mar 2021 01:22:22
User entered 'No (N)'	System	12 Mar 2021 01:22:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-11T17:22:19-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'b2e22366-9b0f-4ad4-af46-b042661358ac'	System	12 Mar 2021 01:22:22
User entered '11 Mar 2021 17:22:19'	System	12 Mar 2021 01:22:22

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-19T12:02:32-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04df5128-468d-439a-9022-6bafd32ff1aa'	System	19 Mar 2021 17:05:11
User entered 'No (N)'	System	19 Mar 2021 17:05:11



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-19T12:02:44-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04df5128-468d-439a-9022-6bafd32ff1aa'	System	19 Mar 2021 17:05:11
User entered 'No (N)'	System	19 Mar 2021 17:05:11

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-19T12:02:48-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '04df5128-468d-439a-9022-6bafd32ff1aa' User entered '19 Mar 2021 12:02:48'	System	19 Mar 2021 17:05:11
	System	19 Mar 2021 17:05:11

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-24T15:15:06-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3261acbf-bf88-4e1a-ab37-36cc24cfbc0'	System	24 Mar 2021 20:15:18
User entered 'No (N)'	System	24 Mar 2021 20:15:18

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-24T15:15:10-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3261acbf-bf88-4e1a-ab37-36cc24fcfb0'	System	24 Mar 2021 20:15:18
User entered 'No (N)'	System	24 Mar 2021 20:15:18

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-24T15:15:14-05:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3261acbf-bf88-4e1a-ab37-36cc24fcfbc0' User entered '24 Mar 2021 15:15:14'	System	24 Mar 2021 20:15:18
	System	24 Mar 2021 20:15:18



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-02T12:00:43-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fa943d9-a6c9-4835-a65e-c3c0d1c4b803' User entered 'No (N)'	System	02 Apr 2021 19:01:05
	System	02 Apr 2021 19:01:05

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-02T12:00:46-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fa943d9-a6c9-4835-a65e-c3c0d1c4b803' User entered 'No (N)'	System	02 Apr 2021 19:01:05

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-02T12:00:51-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '3fa943d9-a6c9-4835-a65e-c3c0d1c4b803'	System	02 Apr 2021 19:01:05
User entered '02 Apr 2021 12:00:51'	System	02 Apr 2021 19:01:05

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-07T08:14:08-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '135e1e28-425d-4329-bd99-72f228012ad3'	System	07 Apr 2021 15:14:26
User entered 'No (N)'	System	07 Apr 2021 15:14:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-07T08:14:16-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '135e1e28-425d-4329-bd99-72f228012ad3'	System	07 Apr 2021 15:14:26
User entered 'No (N)'	System	07 Apr 2021 15:14:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-07T08:14:20-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '135e1e28-425d-4329-bd99-72f228012ad3'	System	07 Apr 2021 15:14:26
User entered '07 Apr 2021 08:14:20'	System	07 Apr 2021 15:14:26

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-14T21:46:55-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '2cd4cc42-f903-42cc-90de-1653f999b05e' User entered 'No (N)'	System	15 Apr 2021 04:47:08
	System	15 Apr 2021 04:47:08



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-14T21:47:00-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '2cd4cc42-f903-42cc-90de-1653f999b05e' User entered 'No (N)'	System	15 Apr 2021 04:47:08

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-14T21:47:04-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '2cd4cc42-f903-42cc-90de-1653f999b05e' User entered '14 Apr 2021 21:47:04'	System	15 Apr 2021 04:47:08
	System	15 Apr 2021 04:47:08

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-22T08:17:03-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'abd194a4-0807-4353-ae87-a36ea662cfb9' User entered 'No (N)'	System	22 Apr 2021 15:17:33
	System	22 Apr 2021 15:17:33

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-22T08:17:20-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'abd194a4-0807-4353-ae87-a36ea662cfb9'	System	22 Apr 2021 15:17:33
User entered 'No (N)'	System	22 Apr 2021 15:17:33

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-04-22T08:17:23-07:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: 'abd194a4-0807-4353-ae87-a36ea662cfb9'	System	22 Apr 2021 15:17:33
User entered '22 Apr 2021 08:17:23'	System	22 Apr 2021 15:17:33



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:46:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:46:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:46:28



**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:46:28

**US3462213**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:42:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:28
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:46:28

US3462213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:42:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-01T10:44:19-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '19c70e8a-5db6-4421-8ee8-511977e88def' User entered 'No (N)'	System	04 Mar 2021 17:15:30
	System	04 Mar 2021 17:15:30

**US3462213**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:45:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (533AF364-A4D2-4C68-98B9-269E542BD37D)', Time: '2021-03-01T10:44:29-08:00', User OID: 'PatientReportedOutcome (US3462213)', ODM File OID: '19c70e8a-5db6-4421-8ee8-511977e88def' User entered '01 Mar 2021 10:44:29'	System	04 Mar 2021 17:15:30
	System	04 Mar 2021 17:15:30

**US3462213**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:41
User entered 'Yes (Y)'		24 Nov 2020 23:42:28

US3462213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:41
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		07 Dec 2020 17:18:54
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call done in window for Day 85.' (Site from System).		24 Nov 2020 23:42:50
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Nov 2020 23:42:28
User entered '12 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 23:42:28



US3462213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:41
User entered 'Contact Made (CONTACT MADE)'		24 Nov 2020 23:42:28

US3462213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:21:41
User entered empty.		24 Nov 2020 23:42:28

**US3462213**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:22:02
User entered 'Yes (Y)'		24 Nov 2020 23:42:19

**US3462213**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:57:28
User entered 'I'	System	24 Nov 2020 23:42:19

**US3462213**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:24:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:11:47

**US3462213**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:24:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:11:47

**US3462213**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:24:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:11:47

US3462213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:24:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:11:47



**US3462213**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:24:23
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 01:11:50

**US3462213**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered 'I'	System	01 Jan 2021 01:11:50

**US3462213**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:21:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:35:47

US3462213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:21:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User closed query 'Per CDM: The treatment date on exposure form in visit 2 is 30 SEP 2020 and Safety call 149 made on 12 JAN 2021 which is 104 days from exposure date which is out of allowed window. Please verify the data and update if appropriate else confirm correct. Thank you. ' (Site from DM).	(b) (4)	
Query 'Per CDM: The treatment date on exposure form in visit 2 is 30 SEP 2020 and Safety call 149 made on 12 JAN 2021 which is 104 days from exposure date which is out of allowed window. Please verify the data and update if appropriate else confirm correct. Thank you. ' answered with '12Jan2021 is exactly Day 149 on the study. Per protocol, this is in window.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:36:52
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		10 Feb 2021 23:55:23
User opened query 'Per CDM: The treatment date on exposure form in visit 2 is 30 SEP 2020 and Safety call 149 made on 12 JAN 2021 which is 104 days from exposure date which is out of allowed window. Please verify the data and update if appropriate else confirm correct. Thank you. ' (Site from DM).		21 Jan 2021 05:37:38
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date is correct as entered.' (Site from System).		21 Jan 2021 05:37:36
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		20 Jan 2021 19:35:57
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	20 Jan 2021 19:35:47

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**US3462213**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 19:35:47

**US3462213**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:21:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:35:47

US3462213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:21:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:35:47

US3462213

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:22:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:02



**US3462213**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered 'I'	System	20 Jan 2021 19:36:02

**US3462213**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:24:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:08:03

US3462213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:24:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 03:12:08
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered.' (Site from System).		22 Feb 2021 23:08:17
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 23:08:03
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 23:08:03

**US3462213**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:42:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:24:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:08:03

US3462213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		30 Mar 2021 21:24:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:08:03

**US3462213**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		31 Mar 2021 20:13:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 23:08:22

**US3462213**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered 'I'	System	22 Feb 2021 23:08:22

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:35
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:21:06



US3462213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:35
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:16:51
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'per source document date is correct unknown why it was done out of window ' (Site from System).		22 Mar 2021 16:21:40
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 16:21:06
User entered '12 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:21:06

US3462213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:38
DataPoint Un-verified.		02 Apr 2021 18:30:37
DataPoint Verified.		02 Apr 2021 18:30:35
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:21:06

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered 'VISIT4'	System	22 Mar 2021 16:21:06

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered empty.	System	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55



**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered empty.	System	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered empty.	System	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered empty.	System	31 Mar 2021 18:06:55



**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:45
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:06:55

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered empty.	System	31 Mar 2021 18:06:55

US3462213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:42:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:42:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:55
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:21:50

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:42:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:30:55
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:21:50

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:31:02
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:22:06

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:31:02
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:22:06



**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:31:02
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered '09:40'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:22:06

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered '12 Mar 2021 09:40'	System	22 Mar 2021 16:22:06

US3462213

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
DataPoint Verified.		02 Apr 2021 18:31:13
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:07:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:22:12

**US3462213**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:27:27
User entered 'I'	System	22 Mar 2021 16:22:12

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:30

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:30

US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:30

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:42:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 00:02:30



US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:42:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:26:30

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:42:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:12:14
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:26:30

US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:42:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:42:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52



US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:42:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User entered empty.	System	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:42:58**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User entered empty.	System	11 Feb 2021 00:02:52

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:09

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:09

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '11:25'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:09

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:42:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User entered '5 Feb 2021 11:25'	System	11 Feb 2021 00:03:09

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:42:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:19



US3462213

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:19

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
DataPoint Verified.		02 Apr 2021 18:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '11:17'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:03:19

**US3462213**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:42:58**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:27:35
User entered '5 Feb 2021 11:17'	System	11 Feb 2021 00:03:19

US3462213

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:42:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User closed query 'Per source AE Log, please add Laryngitis starting on 10Sep2020 to the AE Log.' (Site from CRA).	(b) (4)	11 Feb 2021 23:12:05
Query 'Per source AE Log, please add Laryngitis starting on 10Sep2020 to the AE Log.' answered with 'Entered.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 00:01:31
User opened query 'Per source AE Log, please add Laryngitis starting on 10Sep2020 to the AE Log.' (Site from CRA).		10 Feb 2021 22:38:42
DataPoint Verified.		10 Feb 2021 22:38:05
User entered 'Yes (Y)'		08 Jan 2021 00:18:15

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
Un-reviewed for Safety.		11 Feb 2021 14:19:40
Reviewed for Safety.		08 Jan 2021 10:57:53
User entered 'USA-US093-2021-mRNA-1273-P301000001'	System	08 Jan 2021 10:57:33
User entered 'New'	(b) (4), (b) (6)	08 Jan 2021 10:57:33

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Optic nerve disorders NEC, PT: Optic neuritis, LLT: Optic neuritis - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 11:51:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 11:51:49
User closed query 'Per source progress note dated 18Dec2020, subject reported an AE of Swollen Optic Nerve starting on 15Dec2020. Please clarify that this should be added to the AE Log as a Non-Serious AE. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 06:36:43
DataPoint Verified.		11 Feb 2021 23:15:53
Query 'Per source progress note dated 18Dec2020, subject reported an AE of Swollen Optic Nerve starting on 15Dec2020. Please clarify that this should be added to the AE Log as a Non-Serious AE. ' answered with 'Updated the term here, and added Non-Serious AE as well.' (Site from CRA).		10 Feb 2021 23:34:43
Data point term sent to Coder	System	10 Feb 2021 23:33:48
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 23:33:10
User entered 'nonarteritic ischemic optic nerve neuritis (right eye)' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User opened query 'Per source progress note dated 18Dec2020, subject reported an AE of Swollen Optic Nerve starting on 15Dec2020. Please clarify that this should be added to the AE Log as a Non-Serious AE. ' (Site from CRA).		10 Feb 2021 22:42:49
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Optic disc abnormalities NEC, PT: Papilloedema, LLT: Optic nerve edema - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 13:48:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 13:48:39
Data point term sent to Coder	System	08 Jan 2021 00:29:50

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Swollen Optic Nerve Right Eye'	(b) (4), (b) (6)	08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Yes (Y)'		08 Jan 2021 00:29:19



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:35:29
User closed query 'PV Query: It was reported the subject reported right eye swollen optic nerve starting on 15 Dec 2020. Please assess if the event onset date should be updated to 15 Dec 2020. If no, please state so.' (Site from Safety).		30 Mar 2021 16:26:05
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Query 'PV Query: It was reported the subject reported right eye swollen optic nerve starting on 15 Dec 2020. Please assess if the event onset date should be updated to 15 Dec 2020. If no, please state so.' answered with 'Yes, you're right. Start date amended per query.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:00:36
DataPoint Un-verified.		30 Mar 2021 00:00:21
User entered '15 Dec 2020' reason for change: Data Entry Error		30 Mar 2021 00:00:21
User opened query 'PV Query: It was reported the subject reported right eye swollen optic nerve starting on 15 Dec 2020. Please assess if the event onset date should be updated to 15 Dec 2020. If no, please state so.' (Site from Safety).		18 Feb 2021 20:00:32
DataPoint Verified.		11 Feb 2021 23:15:53
User entered '04 Jan 2021'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User entered 'Yes (Y)'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:25:36
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:13:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:04:13
Signature has been broken.		07 Apr 2021 22:04:13
User entered '27 Jan 2021' reason for change: Data Entry Error		07 Apr 2021 22:04:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '9 Jan 2021' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User entered empty.		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
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).		11 Feb 2021 14:19:31
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 'Date added.' (Site from Safety).		10 Feb 2021 23:34:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		15 Jan 2021 15:17:18
User entered empty.		08 Jan 2021 00:29:19



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Grade 4 (Grade 4)'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Yes (Y)'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		11 Feb 2021 14:19:47
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Date added.' (Site from Safety).		10 Feb 2021 23:35:05
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		10 Feb 2021 23:33:10
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		10 Feb 2021 23:33:10
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 15:17:04
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	08 Jan 2021 00:29:19
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '4 Jan 2021'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 16:26:00
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Report has been sent per query. Please let me know if additional follow-up is needed.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 00:35:46
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:08:09
DataPoint Verified.		11 Feb 2021 23:15:53
User entered '9 Jan 2021' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User entered empty.		08 Jan 2021 00:29:19



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Not Related (NOT RELATED)'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Not Related (NOT RELATED)'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'PV Query: As the subject had already received both the doses of the study drug, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety).		11 Feb 2021 14:19:51
Query 'PV Query: As the subject had already received both the doses of the study drug, please consider updating the action taken with study drug from none to not applicable.' answered with 'Corrected.' (Site from Safety).		10 Feb 2021 23:35:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User opened query 'PV Query: As the subject had already received both the doses of the study drug, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety).		15 Jan 2021 15:17:59
User entered 'None (NONE)'		08 Jan 2021 00:29:19



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information becomes available. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:10:33
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).		30 Mar 2021 16:25:55
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information becomes available. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Con Meds added' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:02:55
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 'All concomitant medications have been added, per query' (Site from Safety).		30 Mar 2021 00:02:40
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information becomes available. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		01 Mar 2021 10:04:41

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Concomitant Medication](#)

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)	18 Feb 2021 20:00:19
User closed query 'Per DM CLR: Other Action Take = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		12 Feb 2021 14:09:10
DataPoint Verified.		11 Feb 2021 23:15:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		10 Feb 2021 23:40:25
' answered with 'Awaiting medical records for detailed CMs.' (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		25 Jan 2021 12:32:27
' (Site from DM).		
User entered 'I'		08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		08 Jan 2021 00:29:19

US3462213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luckinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		11 Feb 2021 14:19:54
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Entered.' (Site from Safety).		10 Feb 2021 23:40:31
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		15 Jan 2021 15:17:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		08 Jan 2021 00:29:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'impaired vision right eye' reason for change: Data Entry Error		10 Feb 2021 23:33:10
User entered empty.		08 Jan 2021 00:29:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = PATIENT WAS DISCHARGED TO HOME ON 09JAN2021 ON ORAL CORTICOSTEROID BURST. 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)	31 Mar 2021 11:12:26
User closed query 'Per DM CLR: Narrative = ECHOCARDIOGRAM AND BRAIN MRI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		31 Mar 2021 11:11:28
User closed query 'Per DM CLR: Narrative = BRAIN ANGIOGRAM . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		31 Mar 2021 11:11:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Query 'Per DM CLR: Narrative = ECHOCARDIOGRAM AND BRAIN MRI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'All procedures have been entered into the Concomitant Procedures page, per query. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:21:37
Query 'Per DM CLR: Narrative = BRAIN ANGIOGRAM . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'All procedures have been entered into the Concomitant Procedures page, per query. ' (Site from DM).		30 Mar 2021 00:21:33
Query 'Per DM CLR: Narrative = PATIENT WAS DISCHARGED TO HOME ON 09JAN2021 ON ORAL CORTICOSTEROID BURST. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'This has been updated in con meds.' (Site from DM).		30 Mar 2021 00:16:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PATIENT WAS DISCHARGED TO HOME ON 09JAN2021 ON ORAL CORTICOSTEROID BURST. 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)	01 Mar 2021 10:04:01
User opened query 'Per DM CLR: Narrative = ECHOCARDIOGRAM AND BRAIN MRI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		01 Mar 2021 10:03:50
User opened query 'Per DM CLR: Narrative = BRAIN ANGIOGRAM . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		01 Mar 2021 10:03:45
DataPoint Verified.		11 Feb 2021 23:15:53
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).		11 Feb 2021 14:20:05
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).		11 Feb 2021 14:20:02
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		11 Feb 2021 14:19:58



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Narrative](#)

Audit	User	Time (GMT)
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 'Awaiting hospital discharge summary.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 23:52:31
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 'Awaiting discharge summary from hospital.' (Site from Safety).		10 Feb 2021 23:52:11
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'No Covid test was done, per patient.' (Site from Safety).		10 Feb 2021 23:50:31
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Feb 2021 23:50:12
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Feb 2021 23:50:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject initially reported to site an AE of Right Eye Swollen Optic Nerve, starting on 15Dec2020. Subject was started on Prednisolone eye drops (1 drop per day). On 04Jan2021, subject's vision deteriorated further, and she was instructed by her ophthalmologist to go to the ER. Subject was admitted to the hospital on 04Jan2021 for testing. Subject's symptoms included eye irritation, blurry vision, and a "dark spot" in her vision. Patient reported no eye pain. Brain angiogram was unremarkable. Echocardiogram and brain MRI were normal. Patient was discharged to home on 09Jan2021 on oral corticosteroid burst. Diagnosis upon discharge was Nonarteritic Ischemic Optic Nerve Neuritis - Right Eye.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 23:50:12
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		15 Jan 2021 15:17:50
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).		15 Jan 2021 15:17:27
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		15 Jan 2021 15:16:50
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	08 Jan 2021 00:29:19
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 00:29:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:29:19

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 00:29:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 00:29:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Optic disc abnormalities NEC, PT: Papilloedema, LLT: Optic nerve edema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 23:35:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 23:35:41
Data point term sent to Coder	System	10 Feb 2021 23:34:54
User entered 'swollen optic nerve right eye'	(b) (4), (b) (6)	10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Yes (Y)'		10 Feb 2021 23:34:03



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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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)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '15 Dec 2020'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User entered empty.	System	10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '4 Jan 2021'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User entered empty.	System	10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		10 Feb 2021 23:34:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 23:34:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 23:34:14
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:03
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 23:34:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 23:34:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 23:34:14
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:03
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 23:34:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 23:34:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 23:34:14
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:34:03
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 23:34:03



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'l'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User entered '0'	System	10 Feb 2021 23:34:03

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13
User entered 'I'	System	10 Feb 2021 23:34:03



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:13

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17

US3462213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:42:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Laryngitis, LLT: Laryngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:03:41
Data point term sent to Coder	System	11 Feb 2021 00:02:15
User entered 'laryngitis'	(b) (4), (b) (6)	11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Yes (Y)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '10 Sep 2020'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User entered empty.	System	11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '25 Oct 2020'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User entered empty.	System	11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Grade 1/Mild (Grade 1/Mild)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'No (N)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Not Related (NOT RELATED)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Not Related (NOT RELATED)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'None (NONE)'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'l'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered '0'		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		11 Feb 2021 00:01:17



**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:15:53
User entered empty.		11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User entered '0'	System	11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17
User entered '1'	System	11 Feb 2021 00:01:17

**US3462213**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:05:17

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:42:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:54:08
User entered 'Yes (Y)'		04 Oct 2020 19:03:23

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:05:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:05:44
Data point term sent to Coder User entered 'FLU VACCINE'	System (b) (4), (b) (6)	04 Oct 2020 19:05:22 04 Oct 2020 19:05:02

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:05:02



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'FLU PROPHYLAXIS'		04 Oct 2020 19:05:02

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'I'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Other (OTHER)'		04 Oct 2020 19:05:02

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'INJECTION'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once (ONCE)'		04 Oct 2020 19:05:02

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Intramuscular (INTRAMUSCULAR)'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:02



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '17 Sep 2020'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '17 Sep 2020'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
User entered empty.	System	04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
User entered empty.	System	04 Oct 2020 19:05:02

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:10
User entered empty.	System	04 Oct 2020 19:05:02



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:06:44
Data point term sent to Coder	System	04 Oct 2020 19:06:23
User entered 'ALBUTEROL'	(b) (4), (b) (6)	04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:36:08
User entered 'Yes (Y)'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'ASTHMA'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '180'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'ug (ug)'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:50



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'		04 Oct 2020 19:05:50

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 1998'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:05:50



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:05:50

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:05:50

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:07:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:07:44
Data point term sent to Coder	System	04 Oct 2020 19:07:23
User entered 'SINGULAIR'	(b) (4), (b) (6)	04 Oct 2020 19:06:32

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:36:32
User entered 'Yes (Y)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'ASTHMA'		04 Oct 2020 19:06:32

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:40:33
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Corrected.' (Site from DM).		06 Jan 2021 18:49:50
DataPoint Un-verified.		06 Jan 2021 18:49:43
User entered '10' reason for change: Data Entry Error		06 Jan 2021 18:49:43
DataPoint Verified.		03 Dec 2020 19:57:31
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		24 Nov 2020 02:47:10
User entered '1'		04 Oct 2020 19:06:32

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:43
User entered 'mg (mg)' reason for change: Data Entry Error		06 Jan 2021 18:49:43
DataPoint Verified.		03 Dec 2020 19:57:31
User entered 'tablet (TABLET)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:06:32



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2010'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:06:32



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:06:32

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:06:32

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:08:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:08:44
Data point term sent to Coder	System	04 Oct 2020 19:08:25
User entered 'SYMBICORT 160/4.5'	(b) (4), (b) (6)	04 Oct 2020 19:07:40

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:36:59
User entered 'Yes (Y)'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'ASTHMA'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'I'		04 Oct 2020 19:07:40



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'puff (PUFF)'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'twice daily (BID)'		04 Oct 2020 19:07:40

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2012'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:07:40



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:07:40

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:07:40

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:09:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:09:44
Data point term sent to Coder	System	04 Oct 2020 19:09:26
User entered 'PRILOSEC'	(b) (4), (b) (6)	04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:37:10
User entered 'Yes (Y)'		04 Oct 2020 19:08:29



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '20'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:08:29



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2005'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:08:29

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:08:29



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:11:45
Data point term sent to Coder	System	04 Oct 2020 19:10:26
User entered 'ZYRTEC'	(b) (4), (b) (6)	04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:37:20
User entered 'Yes (Y)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'SEASONAL AND PERENNIAL ALLERGIC RHINITIS'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '10'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:09



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2006'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:10:09



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:10:09

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:10:09

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:12:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:12:45
Data point term sent to Coder	System	04 Oct 2020 19:11:27
User entered 'ALEVE'	(b) (4), (b) (6)	04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:37:29
User entered 'Yes (Y)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'OCCASIONAL HEADACHES'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '220'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:47



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2002'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:10:47



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:10:47

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:10:47

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Luck singer (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTS YNOM: GLYCOLAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:13:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:13:45
Data point term sent to Coder	System	04 Oct 2020 19:12:27
User entered 'GLYCOLAX'	(b) (4), (b) (6)	04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:37:41
User entered 'Yes (Y)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'OCCASIONAL CONSTIPATION'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '17'		04 Oct 2020 19:11:55



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'g (g)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2006'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:11:55



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:11:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:11:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:00:25
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 Oct 2020 15:00:25
Data point term sent to Coder	System	04 Oct 2020 19:13:28
User entered 'CALCIUM'	(b) (4), (b) (6)	04 Oct 2020 19:12:39

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		23 Oct 2020 12:13:02
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'UPDATED' (Site from DM).		11 Oct 2020 19:38:04
User entered 'Yes (Y)' reason for change: Data Entry Error		11 Oct 2020 19:37:57
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		08 Oct 2020 11:09:17
User entered 'No (N)'		04 Oct 2020 19:12:39



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'SUPPLEMEN T'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '400'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:12:39

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:12:39



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Jun 2006'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:12:39

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:12:39



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:14:45
Data point term sent to Coder	System	04 Oct 2020 19:13:29
User entered 'VITAMIN D3'	(b) (4), (b) (6)	04 Oct 2020 19:13:19

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		23 Oct 2020 12:13:07
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'UPDATED' (Site from DM).		11 Oct 2020 19:38:20
User entered 'Yes (Y)' reason for change: Data Entry Error		11 Oct 2020 19:38:13
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).		08 Oct 2020 11:09:03
User entered 'No (N)'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'SUPPLEMENT'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '2000'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'IU (IU)'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:13:19

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:13:19

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:13:19



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2006'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:13:19



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:13:19

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:13:19

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:57:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:57:20
Data point term sent to Coder	System	04 Oct 2020 19:15:29
User entered 'LIDODERM 5%'	(b) (4), (b) (6)	04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:38:32
User entered 'Yes (Y)'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'OCCASIONAL BACK PAIN'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'I'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Other (OTHER)'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'APPLICATION'		04 Oct 2020 19:14:57



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:14:57

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Topical (TOPICAL)'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN UNK 2011'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:14:57



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:14:57

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:14:57

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: ALGELDRATE;SODIUM ALGINATE, PRODUCTSYNONYM: GAVISCON [ALGELDRATE;SODIUM ALGINATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:56:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:56:42
Data point term sent to Coder	System	04 Oct 2020 19:16:30
User entered 'GAVISCON 80/14.2'	(b) (4), (b) (6)	04 Oct 2020 19:15:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:38:42
User entered 'Yes (Y)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '2'		04 Oct 2020 19:15:55



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'tablet (TABLET)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Nov 2017'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:15:55



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:15:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:15:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:21:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:21:19
Data point term sent to Coder	System	04 Oct 2020 19:17:30
User entered 'MOBIC'	(b) (4), (b) (6)	04 Oct 2020 19:16:36

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:38:51
User entered 'Yes (Y)'		04 Oct 2020 19:16:36



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'OCCASIONAL BACK PAIN'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '15'		04 Oct 2020 19:16:36

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'as needed (PRN)'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:16:36



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Nov 2017'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:16:36

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 19:16:36



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
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 BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:18:45
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Oct 2020 19:18:45
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	04 Oct 2020 19:17:30
User entered 'NORVASC'	(b) (4), (b) (6)	04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:39:02
User entered 'Yes (Y)'		04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'HYPERTENSION'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '10'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'mg (mg)'		04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:06



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Nov 2017'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:17:06



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:17:06

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:17:06

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 19:19:46
Data point term sent to Coder	System	04 Oct 2020 19:18:31
User entered 'FLONASE'	(b) (4), (b) (6)	04 Oct 2020 19:17:52

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:39:12
User entered 'Yes (Y)'		04 Oct 2020 19:17:52

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'SEASONAL AND PERENNIAL ALLERGIC RHINITIS'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '50'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'ug (ug)'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:52



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:17:52

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Nasal (NASAL)'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Dec 2017'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:17:52



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:17:52

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:17:52

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: MAXZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:06:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:06:27
Data point term sent to Coder	System	04 Oct 2020 19:19:31
User entered 'MAXIDE 37.5/25'	(b) (4), (b) (6)	04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)' reason for change: Data Entry Error		11 Oct 2020 19:39:22
User entered 'Yes (Y)'		04 Oct 2020 19:18:49

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'HYPERTENSION'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'I'		04 Oct 2020 19:18:49



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'tablet (TABLET)'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:18:49

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'once daily (QD)'		04 Oct 2020 19:18:49

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Oral (ORAL)'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'UN Nov 2017'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered '0'		04 Oct 2020 19:18:49



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'Yes (Y)'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered empty.		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:57:31
User entered 'No (N)'		04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 19:18:49

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 19:18:49

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 09:18:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 09:18:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 23:17:08
Data point term sent to Coder	System	10 Feb 2021 23:39:56
User entered 'Prednisolone'	(b) (4), (b) (6)	10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'No (N)'		10 Feb 2021 23:39:11



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'right eye swollen optic nerve'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'I'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'Other (OTHER)'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'drop'		10 Feb 2021 23:39:11

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'once daily (QD)'		10 Feb 2021 23:39:11

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered empty.		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'Topical (TOPICAL)'		10 Feb 2021 23:39:11

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered empty.		10 Feb 2021 23:39:11



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered '15 Dec 2020'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered '0'		10 Feb 2021 23:39:11

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:39:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 23:39:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 23:39:16
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 23:39:11
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered '28 Dec 2020'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 23:17:08
User entered 'No (N)'		10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
User entered '1'	System	10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
User entered '1'	System	10 Feb 2021 23:39:11

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:27
User entered '804 (804)'	System	10 Feb 2021 23:39:11



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
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)	29 Mar 2021 23:37:16
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 Mar 2021 23:37:16
Data point term sent to Coder User entered 'Influenza Vaccine'	System (b) (4), (b) (6)	29 Mar 2021 23:35:49 29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Influenza Prophylaxis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'injection'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
User entered empty.	System	29 Mar 2021 23:35:14



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
User entered empty.	System	29 Mar 2021 23:35:14

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:32
User entered empty.	System	29 Mar 2021 23:35:14

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:53:45
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 08:53:45
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 22:08:06 07 Apr 2021 22:07:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:44:30
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 12:44:30
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:37:50
User entered 'Solu-Medrol'	(b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		19 Apr 2021 21:26:17
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:13:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:07:33
Signature has been broken.		07 Apr 2021 22:07:33
User entered 'RIGHT EYE NONARTERITIC ISCHEMIC OPTIC NERVE NEURITIS' reason for change: Data Entry Error		07 Apr 2021 22:07:33
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Swollen Right Optic Nerve'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
User entered empty.	System	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
User entered empty.	System	29 Mar 2021 23:37:20

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:36
User entered empty.	System	29 Mar 2021 23:37:20

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:53:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:53:46
Data point term sent to Coder	System	07 Apr 2021 22:07:05
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 22:06:13
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLU-MEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:44:30
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 12:44:30
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 21:54:02
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:40:52
User entered 'Solu-Medrol'	(b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		19 Apr 2021 21:26:13
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:13:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:06:13
Signature has been broken.		07 Apr 2021 22:06:13
User entered 'RIGHT EYE NONARTERITIC ISCHEMIC OPTIC NERVE NEURITIS' reason for change: Data Entry Error		07 Apr 2021 22:06:13
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Swollen Right Optic Nerve'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '250'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		08 Apr 2021 13:13:05
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'You're right -- I'm changing the indication to the correct AE that fit these dates.' (Site from DM).		07 Apr 2021 22:06:43
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 13:47:11
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '9 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:39:53

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
User entered empty.	System	29 Mar 2021 23:39:53

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
User entered empty.	System	29 Mar 2021 23:39:53

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:40
User entered empty.	System	29 Mar 2021 23:39:53

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 23:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 23:42:21
Data point term sent to Coder	System	29 Mar 2021 23:40:52
User entered 'Atorvastatin'	(b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '40'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '9 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:40:42

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 23:40:42

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 23:40:42

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 23:40:42



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:51:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:51:34
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:44:54
User entered 'Prednisone'	(b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Right Eye Nonarteritic ischemic optic nerve neuritis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '60'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '9 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		08 Apr 2021 13:13:16
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'You're right. The end date of the AE was incorrect, and I've updated it.' (Site from DM).		07 Apr 2021 22:09:14
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 13:47:45
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:43:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
User entered '1'	System	29 Mar 2021 23:43:55



**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
User entered '1'	System	29 Mar 2021 23:43:55

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:49
User entered '804 (804)'	System	29 Mar 2021 23:43:55

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:51:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:51:34
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:45:54
User entered 'Prednisone'	(b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Right Eye Nonarteritic ischemic optic nerve neuritis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '40'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		08 Apr 2021 13:13:38
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'You're right. The end date of the AE was incorrect, and I've updated it.' (Site from DM).		07 Apr 2021 22:09:21
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 13:47:55
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:05

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
User entered '1'	System	29 Mar 2021 23:45:05

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
User entered '1'	System	29 Mar 2021 23:45:05

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:53
User entered '804 (804)'	System	29 Mar 2021 23:45:05

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:51:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 08:51:35
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:45:55
User entered 'Prednisone'	(b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Right Eye Nonarteritic ischemic optic nerve neuritis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '20'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		08 Apr 2021 13:13:43
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'You're right. The end date of the AE was incorrect, and I've updated it.' (Site from DM).		07 Apr 2021 22:09:26
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 13:48:08
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:45:48

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
User entered '1'	System	29 Mar 2021 23:45:48

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
User entered '1'	System	29 Mar 2021 23:45:48

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:48:57
User entered '804 (804)'	System	29 Mar 2021 23:45:48

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:51:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:51:35
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	30 Mar 2021 00:58:52
Data point term sent to Coder	System	29 Mar 2021 23:47:56
User entered 'Prednisone'	(b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Right Eye Nonarteritic ischemic optic nerve neuritis'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '10'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56



US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '23 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		08 Apr 2021 13:13:50
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'You're right. The end date of the AE was incorrect, and I've updated it.' (Site from DM).		07 Apr 2021 22:09:30
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 13:48:17
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
DataPoint Verified.		31 Mar 2021 20:24:12
DataPoint Un-verified.		30 Mar 2021 21:54:02
DataPoint Verified.		30 Mar 2021 21:45:47
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 23:46:56

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
User entered '1'	System	29 Mar 2021 23:46:56

**US3462213**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:42:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
User entered '1'	System	29 Mar 2021 23:46:56

US3462213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:49:02
User entered '804 (804)'	System	29 Mar 2021 23:46:56



US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:42:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:28:01
DataPoint Verified.		31 Mar 2021 20:26:53
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:16:49

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:17:23

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Cerebral Angiogram'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:17:23

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:17:23

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:17:23

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:02
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:07

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:02
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Brain Magnetic Resonance Imaging'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:07

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:02
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:07



US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:02
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:07

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:03
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:50

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:03
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Computed Tomography of Head'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:50

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:03
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:50

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:03
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:19:50

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:05
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:15

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:05
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Visual Analog Scale: Carotid Duplex Bilateral'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:15

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:05
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:15



US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:05
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:15

**US3462213**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:42:58**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:09
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:40

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:09
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Visual Analog Scale: Temporal Arteries'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:40

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:09
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:40

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:09
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:40

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:10
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:57

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:10
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Complete Echocardiogram'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:57

US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:10
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:57



US3462213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:42:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:10
DataPoint Verified.		31 Mar 2021 20:26:24
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:52
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 00:20:57

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'USA-US093-2021-MRNA-1273-P301000001'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Gregg'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Edward'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Lucksinger'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Kerwin'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '1900 Cypress Creek Rd'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'Cedar Park'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'TX'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '78613'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'US'	System	08 Jan 2021 10:58:12



US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:14:28
User entered '3'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
	(b) (4)	
User entered '2'	System	11 Feb 2021 14:22:29
User entered '1'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'USA-US093-2021-MRNA-1273-P301000001'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33



US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Gregg'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Edward'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Lucksinger'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Kerwin'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '1900 Cypress Creek Rd'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'Cedar Park'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'TX'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '78613'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'US'	System	08 Jan 2021 10:58:12



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:14:28
User entered '3'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
	(b) (4)	
User entered '2'	System	11 Feb 2021 14:22:29
User entered '1'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:42:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
User entered '08/Jan/2021 05:58'	System	08 Jan 2021 10:58:12

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:58

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'I'		08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'USA-US093-2021-MRNA-1273-P301000001'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Gregg'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Edward'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Lucksinger'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Kerwin'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '1900 Cypress Creek Rd'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'Cedar Park'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'TX'	(b) (4) System	30 Mar 2021 16:26:37



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '78613'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'US'	System	08 Jan 2021 10:58:12

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:14:28
User entered '3'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
	(b) (4)	
User entered '2'	System	11 Feb 2021 14:22:29
User entered '1'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:42:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered '11/Feb/2021 08:22'	(b) (4) System	11 Feb 2021 14:22:29

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:58

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:22:29

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'USA-US093-2021-MRNA-1273-P301000001'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Gregg'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Edward'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Lucksinger'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Kerwin'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '1900 Cypress Creek Rd'	(b) (4) System	30 Mar 2021 16:26:37



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'Cedar Park'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'TX'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '78613'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'US'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:14:28
User entered '3'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
	(b) (4)	
User entered '2'	System	11 Feb 2021 14:22:29
User entered '1'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:42:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '30/Mar/2021 09:26'	(b) (4) System	30 Mar 2021 16:26:37

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:58

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'USA-US093-2021-MRNA-1273-P301000001'	System	08 Jan 2021 10:57:33



**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Yes (Y)'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'No (N)'	System	08 Jan 2021 10:57:33

US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Gregg'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Edward'	System	08 Jan 2021 10:57:33



US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 16:26:37
Signature has been broken.	System	30 Mar 2021 16:26:37
User entered 'Lucksinger'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:40:50
Reviewed for Safety.		08 Jan 2021 10:58:06
User entered 'Kerwin'	System	08 Jan 2021 10:57:33

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '1900 Cypress Creek Rd'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'Cedar Park'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered 'TX'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:15:01
DataPoint Verified.		02 Apr 2021 18:23:28
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 17:30:26
User entered '78613'	(b) (4) System	30 Mar 2021 16:26:37

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:21:22
DataPoint Verified.		10 Feb 2021 22:40:50
User entered 'US'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:42:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:14:28
User entered '3'	System	30 Mar 2021 16:26:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:02:21
	(b) (4)	
User entered '2'	System	11 Feb 2021 14:22:29
User entered '1'	System	08 Jan 2021 10:58:12

**US3462213**

**Folder: SAE USA-US093-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:42:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:25:14
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:07:15
User entered '08/Apr/2021 12:14'	(b) (4) System	08 Apr 2021 16:14:28



US3462213

Folder: SAE USA-US093-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:42:58

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:25:17
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:07:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:01
User entered 'I'		08 Apr 2021 16:14:28