

US3292158 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:25:42

All time stamps listed in this document are displayed in GMT

US3292158

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 19:08:09

Generated On: 09 Jun 2021 16:25:42

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[Participant ID](#)

US3292158

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

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US3292158

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 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) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 19:08:11

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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) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	UNDESCENDED TESTICLES
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	TESTICLE SURGERY
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	NASAL MUCUS OVER PRODUCTION
Start date (dd MMM yyyy)	UN UNK 1988
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	NASAL MUCUS OVERPRODUCTION SURGERY
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	NOV 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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



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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	TYPE 2 DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	CERVICAL DEGENERATIVE JOINT DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	C5-C7 DEGENERATIVE JOINT DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	TONSILLITIS
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 (30)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	CERVICAL DEGENERATIVE JOINT DISEASE SURGERY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Condition	HYPERCHOLESTERLEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:53
Height (xxx.x)	171.5 cm
Weight (xxx.x)	89.8 kg
BMI (xxx.x)	30.53150 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) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:08:11

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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**

(b) (6)

---

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

**No Risk Identified** False

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

US3292158

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

US3292158

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3292158

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 143903

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 ☐

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Height	ND - Not Done
Weight	ND - Not Done

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:53
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:53
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292158

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

13 AUG 2020

---

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

---



US3292158

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 15:16 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 15:16

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

US3292158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:25:00

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	14:09 (24 HR)
Collection date and time (derived)	13 AUG 2020 14:09

US3292158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:30	13 AUG 2020 14:30
Nasopharyngeal Swab 2	No		

US3292158

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:11

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 AUG 2020 16:00

PC Open Date & Time

13 AUG 2020 15:36

PC Close Date & Time

13 AUG 2020 18:06

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	13 AUG 2020 20:22
PC Open Date & Time	13 AUG 2020 19:01
PC Close Date & Time	14 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:53

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 23:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 00:39

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**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

13 AUG 2020 16:00

PC Open Date & Time

13 AUG 2020 15:36

PC Close Date & Time

13 AUG 2020 18:06

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 20:22

PC Open Date & Time

13 AUG 2020 19:01

PC Close Date & Time

14 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:54

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:05

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 18:11

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 00:40

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 16:01
PC Open Date & Time	13 AUG 2020 15:36
PC Close Date & Time	13 AUG 2020 18:06

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 20:23
PC Open Date & Time	13 AUG 2020 19:01
PC Close Date & Time	14 AUG 2020 11:59



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 19:54
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 23:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Yes ☐

PC Time stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:05
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

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

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 00:40
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:44
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 13:59
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3292158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 SEP 2020

What was the treatment time? (00:00-23:59) 13:29 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 13:29

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

US3292158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 SEP 2020
Collection time (00:00-23:59)	12:55 (24 HR)
Collection date and time (derived)	12 SEP 2020 12:55



US3292158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:08	12 SEP 2020 13:08
Nasopharyngeal Swab 2	No		

US3292158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 14:03

PC Open Date & Time

12 SEP 2020 13:49

PC Close Date & Time

12 SEP 2020 16:19

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °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	12 SEP 2020 23:28
PC Open Date & Time	12 SEP 2020 17:14
PC Close Date & Time	13 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 02:15

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 21:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 23:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 SEP 2020 18:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 14:03

PC Open Date & Time

12 SEP 2020 13:49

PC Close Date & Time

12 SEP 2020 16:19

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

15

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 23:29

PC Open Date & Time

12 SEP 2020 17:14

PC Close Date & Time

13 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

15

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

14 SEP 2020 02:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

14 SEP 2020 21:52

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 23:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 14:04
PC Open Date & Time	12 SEP 2020 13:49
PC Close Date & Time	12 SEP 2020 16:19

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 23:30
PC Open Date & Time	12 SEP 2020 17:14
PC Close Date & Time	13 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 02:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:53
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 23:35
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	14:02 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 14:02
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	14:09 (24 HR)
Collection date and time (derived)	8 OCT 2020 14:09

US3292158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:12

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 12:18:04

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59



US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 13:52:05

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	10 NOV 2020 13:37:54
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 22:05:35

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 19:54:02

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 18:27:08
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 01:24:11

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

<b>TIMEPOINT</b>	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 14:46:44
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 15:24:37

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 22:04:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 14:55:33

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 09:45:53

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

<b>TIMEPOINT</b>	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	16 JAN 2021 11:07:44
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 166

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

No ☒

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 JAN 2021 18:39:30

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 15:24:55

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 19:28:22
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 17:06:59

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

<b>TIMEPOINT</b>	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	20 FEB 2021 19:05:08
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 16:33:28

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 16:53:13

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 14:45:09

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 MAR 2021 12:06:33
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	03 APR 2021 16:56:25
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 APR 2021 16:06:59
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 16:10:33

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 14:30:26

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 15:45:42

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 306

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

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30 JUN 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 327

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

Date and time of submission

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10 JUL 2021 00:01

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14 JUL 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

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04 AUG 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

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11 AUG 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

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18 AUG 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 376

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

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01 SEP 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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 ☐

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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19 MAR 2022 00:01

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23 MAR 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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30 MAR 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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13 APR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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16 APR 2022 00:01

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20 APR 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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23 APR 2022 00:01

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27 APR 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 656

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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 ☐

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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13 JUL 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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20 JUL 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 712

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 761

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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21 SEP 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

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01 OCT 2022 00:01

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05 OCT 2022 23:59



US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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12 OCT 2022 23:59

US3292158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

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

**US3292158**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

**US3292158**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 16:25:42**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:33:42

US3292158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292158

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

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*

US3292158

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:25:07

Generated On: 09 Jun 2021 16:25:42

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
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US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:25:07

Generated On: 09 Jun 2021 16:25:42

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) \_\_\_\_\_

US3292158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:25:01

Generated On: 09 Jun 2021 16:25:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



US3292158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:25:01

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	12 MAR 2021 14:50

US3292158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:25:00

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:04:41

Generated On: 09 Jun 2021 16:25:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292158

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:04:41

Generated On: 09 Jun 2021 16:25:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292158**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3292158**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292158

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:25:42

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"/>

**US3292158**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:25:42**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3292158

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

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

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3292158

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 16:25:00

Generated On: 09 Jun 2021 16:25:42

Date of updated informed consent (dd MMM yyyy) 21 JAN 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) 21 JAN 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 \_\_\_\_\_

US3292158

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

15:07 (24 HR)

Collection date and time (derived)

21 JAN 2021 15:07

US3292158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	15:16
Collection Date and Time (derived)	21 JAN 2021 15:16

US3292158

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 16:25:00

Generated On: 09 Jun 2021 16:25:42

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

AEID	USA-US072-2021-MRNA-1273-P30 1000019
Adverse event	EXACERBATION OF COPD
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	29 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

SUBJECT ANSWERED "YES" IN  
EDINARY ON 28MAR2021 TO  
QUESTION ABOUT SEEING A  
HEALTHCARE PROVIDER.  
UPON CONTACTING SUBJECT,  
HE STATED THAT HE HAD  
BEEN ADMITTED TO THE  
HOSPITAL ON 27MAR2021 DUE  
TO EXACERBATION OF COPD  
STARTING ON  
26MAR2021--UNABLE TO  
BREATHE EASILY. SUBJECT  
WAS ADMITTED TO THE VA  
HOSPITAL AND HAS RECEIVED  
STEROIDS AND ANTIBIOTICS.  
SUBJECT UNABLE TO NAME  
THOSE MEDICATIONS AT THIS  
TIME. AS OF 29MAR21, SUBJECT  
STATES HE EXPECTS TO BE  
DISCHARGED THIS EVENING,  
BUT IS STILL ADMITTED AS OF  
LAST CONVERSATION.  
PATIENT WAS ALSO ASKED IF  
ANYTHING IN PARTICULAR  
MADE HIS CONDITION WORSE,  
TO WHICH THE PATIENT  
REPLIED, "SOUTH TEXAS  
ALLERGY SEASON". MEDICAL  
RECORDS WILL BE REQUESTED  
AS SOON AS POSSIBLE AND  
THIS REPORT WILL BE  
UPDATED.

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



US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

AEID	USA-US072-2021-MRNA-1273-P30 1000019
Adverse event	EXACERBATION OF COPD
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)	7 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 APR 2021
Hospital Discharge Date (dd MMM yyyy)	09 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

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

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

---

CALLED PATIENT 08APR21 TO  
FOLLOW UP ON PREVIOUS SAE.  
PATIENT STATES HE HAS BEEN  
HOSPITALIZED ONCE AGAIN  
FOR THE SAME CONDITION.  
STATES ON THE EVENING OF  
07APR21, HE WAS UNABLE TO  
BREATHE COMFORTABLY OR  
CATCH HIS BREATH.  
PRESENTED TO ER AND WAS  
ADMITTED. NO FURTHER  
INFORMATION AVAILABLE AT  
THIS TIME.

---

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

---

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

---

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

Yes ☒

No ☐

---

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

---

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication RHINORRHEA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASAL	
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED EDEMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

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



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication RHINORRHEA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication NIACIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 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 (8)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication TADALAFIL

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (10)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication TROTROPUM

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	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 MAY 2018	
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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 90

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

4 TIMES A DAY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	UN MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication TRAZODONE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication BUDESONIDE/FORMOTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	UN MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 300

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) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input 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) 28 Apr 2021 13:36:31

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Name of Medication CARBOXYMETHYLCELLULOSE

Prophylaxis Yes ☐  
No ☒

Indication DRY EYES

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 (15)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication ENALAPRIL

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication EZETIMIBE

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTERLEMIA

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication FERROUS GLUCONATE

Prophylaxis Yes ☐  
No ☒

Indication ANEMIA

Dose per administration 325

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 (19)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication CHOLECALCIFEROL D-3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 25

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

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 (21)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		IMPANT
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF COPD

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF COPD

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:36:31

Generated On: 09 Jun 2021 16:25:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 19:08:10

Generated On: 09 Jun 2021 16:25:42

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:25:42

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:25:42

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:25:42

SAEID	USA-US072-2021-MRNA-1273-P301000019
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:25:42

SAEID	USA-US072-2021-MRNA-1273-P301000019
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/MAR/2021 06:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:25:42

SAEID	USA-US072-2021-MRNA-1273-P301000019
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 16:14
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

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:25:42

SAEID	USA-US072-2021-MRNA-1273-P301000019
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 14:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:25:42

SAEID	USA-US072-2021-MRNA-1273-P301000019
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAY/2021 05:59
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

US3292158 (Prod: Clinical Trials of Texas, Inc)

**US3292158**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:25:42**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:14:52
User entered 'US3292158'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:29:32

**US3292158**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:41:44

US3292158

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:29:33

**US3292158**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Aug 2020 12:41:44

**US3292158**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'SCRN'	System	17 Aug 2020 12:41:44

US3292158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:29:34

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '58'	(b) (4), (b) (6)	17 Aug 2020 12:41:55



US3292158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'YEARS'	System	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '58'	System	13 Aug 2020 20:36:40

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55



**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:25:42**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:41:55

**US3292158**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 20:36:40

US3292158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:42

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Aug 2020'	System	13 Aug 2020 20:36:40

US3292158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:42

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2020'	System	13 Aug 2020 20:36:40



**US3292158**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:25:42**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	13 Aug 2020 20:36:40

US3292158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:42

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 20:36:40

**US3292158**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:25:42**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:36:40

**US3292158**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:25:42**

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:36:40

**US3292158**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:25:42**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 20:36:40

US3292158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 18:29:33

US3292158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'I'	System	13 Aug 2020 20:36:51

US3292158

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:25:42

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 20:36:51



**US3292158**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 16:25:42**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:42:01

US3292158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:52:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:52:22
Data point term sent to Coder	System	17 Aug 2020 12:43:44
User entered 'Codeine intolerance'	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1990'	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:42:45

**US3292158**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1990'	System	17 Aug 2020 12:42:45



US3292158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1990'	System	17 Aug 2020 12:42:45

US3292158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:42:45

US3292158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:42:45

US3292158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 22:58:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:58:17
Data point term sent to Coder	System	17 Aug 2020 12:43:44
User entered 'Valium intolerance'	(b) (4), (b) (6)	17 Aug 2020 12:43:00

US3292158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1990'	(b) (4), (b) (6)	17 Aug 2020 12:43:00

**US3292158**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:00

**US3292158**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:43:00

**US3292158**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:43:00



**US3292158**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:00

US3292158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1990'	System	17 Aug 2020 12:43:00

**US3292158**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1990'	System	17 Aug 2020 12:43:00

US3292158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:00

US3292158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:00

US3292158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:41:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:41:12
Data point term sent to Coder	System	17 Aug 2020 12:43:46
User entered 'Gabapentin intolerance'	(b) (4), (b) (6)	17 Aug 2020 12:43:24

US3292158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1990'	(b) (4), (b) (6)	17 Aug 2020 12:43:24

**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:24



**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:43:24

**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:43:24

**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:24

**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1990'	System	17 Aug 2020 12:43:24

US3292158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1990'	System	17 Aug 2020 12:43:24

US3292158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:24

**US3292158**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:24

US3292158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:44:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:44:12
Data point term sent to Coder	System	17 Aug 2020 12:43:45
User entered 'Drug allergy to statins'	(b) (4), (b) (6)	17 Aug 2020 12:43:37



**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2015'	(b) (4), (b) (6)	17 Aug 2020 12:43:37

**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:43:37

**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:43:37

**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:43:37

**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:37

US3292158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2015'	System	17 Aug 2020 12:43:37

US3292158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2015'	System	17 Aug 2020 12:43:37

US3292158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:37



**US3292158**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:37

US3292158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:46:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:46:18
Data point term sent to Coder	System	17 Aug 2020 12:44:46
User entered 'Seasonal allergies'	(b) (4), (b) (6)	17 Aug 2020 12:43:48

US3292158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1972'	(b) (4), (b) (6)	17 Aug 2020 12:43:48

**US3292158**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:48

**US3292158**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:43:48

**US3292158**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:43:48

**US3292158**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:43:48

US3292158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1972'	System	17 Aug 2020 12:43:48



**US3292158**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1972'	System	17 Aug 2020 12:43:48

US3292158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:48

US3292158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:43:48

US3292158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Reproductive tract and breast disorders congenital, HLT: Male reproductive tract disorders congenital, PT: Cryptorchism, LLT: Undescended testis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 23:04:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:04:22
Data point term sent to Coder	System	17 Aug 2020 12:44:46
User entered 'Undescended testicles'	(b) (4), (b) (6)	17 Aug 2020 12:44:25

US3292158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:44:25



US3292158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:44:25

US3292158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:44:25

**US3292158**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:44:25

US3292158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Testicular and scrotal therapeutic procedures, PT: Testicular operation, LLT: Testicular operation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Aug 2020 23:19:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 23:19:40
Data point term sent to Coder	System	17 Aug 2020 12:44:47
User entered 'Testicle surgery'	(b) (4), (b) (6)	17 Aug 2020 12:44:39

US3292158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:44:39

**US3292158**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:44:39



**US3292158**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:44:39

**US3292158**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:44:39

**US3292158**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:44:39

US3292158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:44:39

US3292158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:44:39

**US3292158**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:44:39

US3292158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:44:39

US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:49:15
Data point term sent to Coder	System	17 Aug 2020 12:47:48
User entered 'Tonsillectomy'	(b) (4), (b) (6)	17 Aug 2020 12:46:57



US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:46:57

**US3292158**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:46:57

**US3292158**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:46:57

**US3292158**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1973'	(b) (4), (b) (6)	17 Aug 2020 12:46:57

**US3292158**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:46:57

US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:46:57

US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:46:57

US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1973'	System	17 Aug 2020 12:46:57



US3292158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1973'	System	17 Aug 2020 12:46:57

US3292158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Nasal mucus increased - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 00:19:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 00:19:13
Data point term sent to Coder	System	17 Aug 2020 12:47:49
User entered 'Nasal mucus over production'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

US3292158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1988'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

**US3292158**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

**US3292158**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

**US3292158**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

**US3292158**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:47:17

US3292158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1988'	System	17 Aug 2020 12:47:17



US3292158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1988'	System	17 Aug 2020 12:47:17

**US3292158**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2018'	System	17 Aug 2020 12:47:17

US3292158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2018'	System	17 Aug 2020 12:47:17

US3292158

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal operation, LLT: Nasal operation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Nov 2020 05:26:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:26:09
Data point term sent to Coder	System	18 Aug 2020 19:06:06
User entered 'Nasal Mucus Overproduction Surgery' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:05:21
Data point term sent to Coder	System	17 Aug 2020 12:47:48
User entered 'Turboid reduction'	(b) (4), (b) (6)	17 Aug 2020 12:47:45

**US3292158**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1988'	(b) (4), (b) (6)	17 Aug 2020 12:47:45

**US3292158**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:47:45

**US3292158**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:47:45

**US3292158**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un Nov 1988'	(b) (4), (b) (6)	17 Aug 2020 12:47:45



**US3292158**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:47:45

US3292158

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1988'	System	17 Aug 2020 12:47:45

US3292158

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1988'	System	17 Aug 2020 12:47:45

US3292158

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Nov 1988'	System	17 Aug 2020 12:47:45

US3292158

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1988'	System	17 Aug 2020 12:47:45

US3292158

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: CABG - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:49:15
Data point term sent to Coder	System	17 Aug 2020 12:48:50
User entered 'CABG'	(b) (4), (b) (6)	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:48:01



**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:48:01

**US3292158**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:48:01

US3292158

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:48:01

US3292158

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:48:01

US3292158

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal operation, LLT: Nasal operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Nov 2020 05:26:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:26:09
Data point term sent to Coder	System	18 Aug 2020 19:06:06
User entered 'Nasal Mucus Overproduction Surgery' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:05:49
Data point term sent to Coder	System	17 Aug 2020 12:48:53
User entered 'Tubroid reduction'	(b) (4), (b) (6)	17 Aug 2020 12:48:51



**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 12:48:51

**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:48:51

**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:48:51

**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 12:48:51

**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:48:51

US3292158

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2018'	System	17 Aug 2020 12:48:51

**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2018'	System	17 Aug 2020 12:48:51

US3292158

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2018'	System	17 Aug 2020 12:48:51



**US3292158**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2018'	System	17 Aug 2020 12:48:51

US3292158

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
Data point term sent to Coder	System	17 Aug 2020 12:49:53
User entered 'Farsighted'	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:49:03



US3292158

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:49:03

US3292158

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:03

**US3292158**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:03

US3292158

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please specify the location of Tinnitus (Right, Left or Bilateral). Update Med History eCRF as appropriate.	(b) (4), (b) (6)	08 Oct 2020 11:24:42
' (Site from DM).		
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 14:14:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 14:14:54
Query 'Per DM CLR: Please specify the location of Tinnitus (Right, Left or Bilateral). Update Med History eCRF as appropriate.	Victoria Hernandez (b) (4)	24 Sep 2020 14:14:23
' answered with 'UPDATED' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 14:14:22
Coding entries removed.	Victoria Hernandez (b) (4)	24 Sep 2020 14:14:18
	(b) (4)	
User entered 'BILATERAL TINNITUS' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:14:18
User opened query 'Per DM CLR: Please specify the location of Tinnitus (Right, Left or Bilateral). Update Med History eCRF as appropriate.	(b) (4), (b) (6)	22 Sep 2020 10:28:44
' (Site from DM).		
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
Data point term sent to Coder	System	17 Aug 2020 12:49:54
User entered 'Tinnitus'	(b) (4), (b) (6)	17 Aug 2020 12:49:15

**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2005'	(b) (4), (b) (6)	17 Aug 2020 12:49:15

**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:15

**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:49:15

**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:49:15



**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:15

US3292158

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2005'	System	17 Aug 2020 12:49:15

US3292158

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2005'	System	17 Aug 2020 12:49:15

US3292158

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:15

**US3292158**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:15

US3292158

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:25:32
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Hearing impaired - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 18:08:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 18:08:52
Data point term sent to Coder	System	24 Sep 2020 14:15:25
Query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 14:15:18
Coding entries removed.	Victoria Hernandez (b) (4)	24 Sep 2020 14:15:14
User entered 'BILATERAL HEARING IMPARIED' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:15:14
User opened query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 10:29:10
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Hearing impaired - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:47:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 16:47:14
Data point term sent to Coder	System	17 Aug 2020 12:49:55
User entered 'Hearing imparied'	(b) (4), (b) (6)	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2017'	(b) (4), (b) (6)	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:27



**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:27

US3292158

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2017'	System	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2017'	System	17 Aug 2020 12:49:27

**US3292158**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:27

US3292158

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:27

US3292158

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:51:15
Data point term sent to Coder	System	17 Aug 2020 12:49:55
User entered 'COPD'	(b) (4), (b) (6)	17 Aug 2020 12:49:36



**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un Apr 2018'	(b) (4), (b) (6)	17 Aug 2020 12:49:36

**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:36

**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:49:36

**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:49:36

**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:49:36

US3292158

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Apr 2018'	System	17 Aug 2020 12:49:36

US3292158

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2018'	System	17 Aug 2020 12:49:36

**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:36



**US3292158**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:49:36

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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)	18 Aug 2020 23:26:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:40
Data point term sent to Coder	System	18 Aug 2020 19:16:42
User entered 'depression'	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 2019'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:16:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2019'	System	18 Aug 2020 19:16:08
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15



US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	18 Aug 2020 19:16:08
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:16:08
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:16:08
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:15:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Aug 2020 13:02:15

US3292158

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 12:52:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:52:18
Data point term sent to Coder System	(b) (4), (b) (6)	17 Aug 2020 12:50:55
User entered 'CAD'	(b) (4), (b) (6)	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:50:44



**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:50:44

**US3292158**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:50:44

US3292158

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:50:44

US3292158

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarct - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 12:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:53:14
Data point term sent to Coder System	(b) (4), (b) (6)	17 Aug 2020 12:51:59
User entered 'Myocardial infarct'	(b) (4), (b) (6)	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:51:00



**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:51:00

US3292158

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:51:00

**US3292158**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:51:00

US3292158

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:51:00

US3292158

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per MM: Please provide standard diagnosis' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:08:58
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:35:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:35:26
Data point term sent to Coder	System	05 Oct 2020 15:34:40
Query 'Per MM: Please provide standard diagnosis' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:34:37
Coding entries removed.		05 Oct 2020 15:34:31
User entered 'Peripheral arterial disease' reason for change: Data Entry Error		05 Oct 2020 15:34:31
User opened query 'Per MM: Please provide standard diagnosis' (Site from DM).		05 Oct 2020 10:56:40
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - version MedDRA\23.0.	Coder Import (b) (4)	23 Aug 2020 13:59:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Aug 2020 13:59:44
Data point term sent to Coder	System	17 Aug 2020 12:51:57
User entered 'PAD'	(b) (4), (b) (6)	17 Aug 2020 12:51:12



**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2012'	(b) (4), (b) (6)	17 Aug 2020 12:51:12

**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:51:12

**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:51:12

**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:51:12

**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:51:12

US3292158

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2012'	System	17 Aug 2020 12:51:12

**US3292158**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2012'	System	17 Aug 2020 12:51:12

US3292158

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:51:12



US3292158

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:51:12

US3292158

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please specify the location of Edema. Update Med History eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:25:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Generalised oedema, LLT: Generalized edema - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 14:16:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	24 Sep 2020 14:16:53
Data point term sent to Coder	System	24 Sep 2020 14:16:27
Query 'Per DM CLR: Please specify the location of Edema. Update Med History eCRF as appropriate.	Victoria Hernandez (b) (4)	24 Sep 2020 14:16:17
' answered with 'UPDATED' (Site from DM).	(b) (4)	
Coding entries removed.	Victoria Hernandez (b) (4)	24 Sep 2020 14:16:13
User entered 'GENERALIZED EDEMA' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	24 Sep 2020 14:16:13
User opened query 'Per DM CLR: Please specify the location of Edema. Update Med History eCRF as appropriate.	(b) (4), (b) (6)	22 Sep 2020 10:29:25
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	17 Aug 2020 12:53:14
Data point term sent to Coder	System	17 Aug 2020 12:53:00
User entered 'Edema'	(b) (4), (b) (6)	17 Aug 2020 12:52:08

US3292158

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Dawn Killian (b) (4)	18 Aug 2020 19:11:42
User entered 'un UNK 2014'	(b) (4)	
	(b) (4), (b) (6)	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2019'	System	18 Aug 2020 19:11:42
User entered 'Jan 2014'	System	17 Aug 2020 12:52:08



**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	18 Aug 2020 19:11:42
User entered '2014'	System	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:08

**US3292158**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:08

US3292158

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:53:14
Data point term sent to Coder	System	17 Aug 2020 12:53:00
User entered 'GERD'	(b) (4), (b) (6)	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2013'	(b) (4), (b) (6)	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:52:16



**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:16

US3292158

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2013'	System	17 Aug 2020 12:52:16

US3292158

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2013'	System	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:16

**US3292158**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:16

US3292158

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:53:14
Data point term sent to Coder	System	17 Aug 2020 12:53:01
User entered 'Type 2 diabetes mellitus'	(b) (4), (b) (6)	17 Aug 2020 12:52:35

US3292158

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2016'	(b) (4), (b) (6)	17 Aug 2020 12:52:35

**US3292158**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:35



**US3292158**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:52:35

**US3292158**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:52:35

**US3292158**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:52:35

US3292158

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2016'	System	17 Aug 2020 12:52:35

US3292158

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2016'	System	17 Aug 2020 12:52:35

**US3292158**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:35

US3292158

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:52:35

US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Spinal osteoarthritis, LLT: Cervical spine degeneration - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 21:25:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 21:25:18
Data point term sent to Coder	System	17 Aug 2020 12:55:05
User entered 'Cervical degenerative joint disease'	(b) (4), (b) (6)	17 Aug 2020 12:55:04



US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2002'	(b) (4), (b) (6)	17 Aug 2020 12:55:04

US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:55:04

**US3292158**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 12:55:04

**US3292158**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2002'	(b) (4), (b) (6)	17 Aug 2020 12:55:04

**US3292158**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:55:04

US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	17 Aug 2020 12:55:04

US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	17 Aug 2020 12:55:04

**US3292158**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	17 Aug 2020 12:55:04



US3292158

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	17 Aug 2020 12:55:04

US3292158

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 12:57:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:57:07
Data point term sent to Coder	System	17 Aug 2020 12:56:07
User entered 'Carpal tunnel syndrome'	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2014'	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 12:55:16

**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2014'	System	17 Aug 2020 12:55:16



**US3292158**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2014'	System	17 Aug 2020 12:55:16

US3292158

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:55:16

US3292158

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 12:55:16

US3292158

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of cervical spine - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 20:28:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:28:10
Data point term sent to Coder	System	17 Aug 2020 13:01:20
User entered 'C5-C7 degenerative joint disease'	(b) (4), (b) (6)	17 Aug 2020 13:00:30

US3292158

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2002'	(b) (4), (b) (6)	17 Aug 2020 13:00:30

**US3292158**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:00:30

**US3292158**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:00:30

**US3292158**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2002'	(b) (4), (b) (6)	17 Aug 2020 13:00:30



**US3292158**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:00:30

US3292158

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	17 Aug 2020 13:00:30

**US3292158**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	17 Aug 2020 13:00:30

US3292158

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	17 Aug 2020 13:00:30

US3292158

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	17 Aug 2020 13:00:30

US3292158

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Cystitis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 23:03:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:03:21
Data point term sent to Coder	System	17 Aug 2020 13:02:22
User entered 'UTI (cystitis)'	(b) (4), (b) (6)	17 Aug 2020 13:01:31

**US3292158**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 13:01:31

**US3292158**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:01:31



**US3292158**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:01:31

**US3292158**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 13:01:31

**US3292158**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:01:31

US3292158

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2019'	System	17 Aug 2020 13:01:31

US3292158

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	17 Aug 2020 13:01:31

US3292158

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2019'	System	17 Aug 2020 13:01:31

US3292158

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	17 Aug 2020 13:01:31

US3292158

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 06:45:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 06:45:22
Data point term sent to Coder	System	17 Aug 2020 13:40:26
User entered 'Rhionrrhea'	(b) (4), (b) (6)	17 Aug 2020 13:39:45



**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'un UNK 1972'	(b) (4), (b) (6)	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1972'	System	17 Aug 2020 13:39:45

**US3292158**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1972'	System	17 Aug 2020 13:39:45

US3292158

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 13:39:45



US3292158

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	17 Aug 2020 13:39:45

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:25:47
Data point term sent to Coder	System	18 Aug 2020 19:00:47
User entered 'tonsillitis'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 1986'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 18:59:55

**US3292158**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 18:59:55

**US3292158**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 1986'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1986'	System	18 Aug 2020 18:59:55



US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1986'	System	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 1986'	System	18 Aug 2020 18:59:55

**US3292158**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '1986'	System	18 Aug 2020 18:59:55

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint surgery, LLT: Joint surgery - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:50:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:50:39
Data point term sent to Coder	System	18 Aug 2020 19:15:36
User entered 'cervical degenerative joint disease surgery'	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 2002'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:08:35
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 2002'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:08:35
	(b) (4)	



US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4)	
	Dawn Killian (b) (4)	18 Aug 2020 19:14:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2002'	System	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35

US3292158

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2002'	System	18 Aug 2020 19:14:42
DataPoint activated with code reason code Data required.	Dawn Killian (b) (4)	18 Aug 2020 19:14:22
DataPoint inactivated with code reason code Data not required.	Dawn Killian (b) (4)	18 Aug 2020 19:08:35

US3292158

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:50
Data point term sent to Coder	System	18 Aug 2020 19:18:46
User entered 'erectile dysfunction'	Dawn Killian (b) (4)	18 Aug 2020 19:17:56

US3292158

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN Jul 2020'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:17:56

**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:17:56



**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:17:56

**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:17:56

**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:17:56

US3292158

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jul 2020'	System	18 Aug 2020 19:17:56

**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2020'	System	18 Aug 2020 19:17:56

**US3292158**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:17:56

US3292158

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:17:56

US3292158

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 23:27:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:27:01
Data point term sent to Coder	System	18 Aug 2020 19:21:56
User entered 'dry eyes'	Dawn Killian (b) (4)	18 Aug 2020 19:21:23
	(b) (4)	



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Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN Dec 2019'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:21:23

**US3292158**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:21:23

**US3292158**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:21:23

**US3292158**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:21:23

US3292158

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:21:23

US3292158

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Dec 2019'	System	18 Aug 2020 19:21:23

US3292158

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	18 Aug 2020 19:21:23

US3292158

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:21:23



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Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:21:23

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please specify the type of Anemia. Update Med History eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:26:06
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anaemia - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 19:59:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 19:59:34
Data point term sent to Coder	System	24 Sep 2020 14:13:20
Query 'Per DM CLR: Please specify the type of Anemia. Update Med History eCRF as appropriate.	Victoria Hernandez (b) (4)	24 Sep 2020 14:12:33
' answered with 'UPDATED' (Site from DM).	(b) (4)	
Coding entries removed.	Victoria Hernandez (b) (4)	24 Sep 2020 14:12:20
User entered 'IRON DEFICENCY ANMEIA'	(b) (4)	
reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:12:20
User opened query 'Per DM CLR: Please specify the type of Anemia. Update Med History eCRF as appropriate.	(b) (4), (b) (6)	22 Sep 2020 10:29:46
' (Site from DM).		
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:30:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:30:13
Data point term sent to Coder	System	18 Aug 2020 19:25:11
User entered 'Anmeia'	Dawn Killian (b) (4)	18 Aug 2020 19:24:30
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'UN UNK 2019'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:24:30

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:24:30

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:24:30

**US3292158**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:24:30

**US3292158**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4)	18 Aug 2020 19:24:30

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'Jan 2019'	System	18 Aug 2020 19:24:30



**US3292158**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 16:25:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '2019'	System	18 Aug 2020 19:24:30

**US3292158**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:24:30

US3292158

Folder: Screening

Form: Medical History (33)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	18 Aug 2020 19:24:30

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Sep 2020 14:19:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 14:19:45
Data point term sent to Coder	System	24 Sep 2020 14:18:31
User entered 'HYPERTENSION'	Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20

**US3292158**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'l'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20

**US3292158**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 09 Jun 2021 16:25:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20

**US3292158**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20



**US3292158**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:18:20

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:18:20

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:18:20

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:18:20

US3292158

Folder: Screening

Form: Medical History (34)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:18:20

US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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)	24 Sep 2020 14:21:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 14:21:58
Data point term sent to Coder	System	24 Sep 2020 14:20:42
User entered 'HYPERCHOLESTERLEMIA'	Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46
	(b) (4)	

US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46

**US3292158**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'l'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46



US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46

**US3292158**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 09 Jun 2021 16:25:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46

**US3292158**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Victoria Hernandez (b) (4)	24 Sep 2020 14:19:46

US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:19:46

US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:19:46

**US3292158**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 09 Jun 2021 16:25:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:19:46

US3292158

Folder: Screening

Form: Medical History (35)

Generated On: 09 Jun 2021 16:25:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	24 Sep 2020 14:19:46

**US3292158**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:03:03



US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:03:03

**US3292158**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13:53'	(b) (4), (b) (6)	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '13 Aug 2020 13:53'	System	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '171.5' cm	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:03:03
DataPoint set to visible.	System	13 Aug 2020 20:36:51

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '89.8' kg	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:03:03
DataPoint set to visible.	System	13 Aug 2020 20:36:51

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
Amendment Manager: User entered '30.53150'	System	16 Sep 2020 23:55:51
User entered '30.5'	System	17 Aug 2020 13:03:03
DataPoint set to visible.	System	13 Aug 2020 20:36:51

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'kg/m2'	System	17 Aug 2020 13:03:03
DataPoint set to visible.	System	13 Aug 2020 20:36:51

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	(b) (4), (b) (6) 17 Aug 2020 13:03:12
User entered missing code ND - Not Done.		17 Aug 2020 13:03:03



US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
Un-reviewed for Data Management.	(b) (4), (b) (6)	18 Aug 2020 07:05:00
Reviewed for Data Management.		18 Aug 2020 07:04:55
User closed query 'Data is required. Please provide.' (Site from System).		18 Aug 2020 06:57:37
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		17 Aug 2020 13:03:11
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 13:03:03
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

**US3292158**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

**US3292158**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'bpm'	System	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'breaths/min'	System	17 Aug 2020 13:03:03

**US3292158**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'mmHg'	System	17 Aug 2020 13:03:03



US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'mmHg'	System	17 Aug 2020 13:03:03

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37

US3292158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37

US3292158

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:03:20

US3292158

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 16:06:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		12 Sep 2020 19:45:15
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:03:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20



US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20



US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

**US3292158**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:25:42**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered (b) (6)	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20



US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 13:04:20

US3292158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:04:20

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:30

US3292158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:04:30

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[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 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Aug 2020 13:04:30

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'VISIT1'	System	17 Aug 2020 13:04:30

US3292158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:42

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:54:18



US3292158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:16:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:16:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 19:54:18
User entered '143903' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:54:18

US3292158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 19:54:18

US3292158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:42

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:49

US3292158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:42

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:49

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:25:42**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:49

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:25:42**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:04:49

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:25:42**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:04:49

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:25:42**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:06:24



US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:25:42**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:25:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13:53'	(b) (4), (b) (6)	17 Aug 2020 13:05:24



US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '13 Aug 2020 13:53'	System	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '36.4' C	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '94'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'bpm'	System	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'breaths/min'	System	17 Aug 2020 13:05:24



US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '120'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '81'	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	17 Aug 2020 13:05:24

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:33:26



US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	(b) (4), (b) (6)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can occur 30 minute post dose' (Site from System).		17 Aug 2020 18:10:14
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 13:33:49
User entered '15:53'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '13 Aug 2020 15:53'	System	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '36.1' C	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '95'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'bpm'	System	17 Aug 2020 13:33:26



US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'breaths/min'	System	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '135'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '89'	(b) (4), (b) (6)	17 Aug 2020 13:33:26

US3292158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	17 Aug 2020 13:33:26

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:25:42**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:34:26

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:25:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:34:26



US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '15:16'	(b) (4), (b) (6)	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '13 Aug 2020 15:16'	System	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Aug 2020 20:37:32



US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'ONCE'	System	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 20:37:32

US3292158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:34:43

US3292158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User closed query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "CRC to provide", however, there was nothing provided in the query response. Please leave this query open until the shipping information can be added to the query response, as appropriate.' (Site from DM). User signature succeeded.	(b) (4)	19 Apr 2021 12:49:17
	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "CRC to provide", however, there was nothing provided in the query response. Please leave this query open until the shipping information can be added to the query response, as appropriate.' answered with 'As per source, sample was collected as indicated here. However, after following up with PPD and on-site lab, requisition and shipping information cannot be located.' (Site from DM).	Antonio Gutierrez (b) (4)	08 Apr 2021 15:05:13
	(b) (4), (b) (6)	
User opened query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "CRC to provide", however, there was nothing provided in the query response. Please leave this query open until the shipping information can be added to the query response, as appropriate.' (Site from DM).		11 Dec 2020 12:38:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM).		11 Dec 2020 12:38:07

US3292158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' answered with 'CRC to provide' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you' (Site from DM). User entered '13 Aug 2020'	Dawn Killian (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 20:43:44 17 Nov 2020 08:20:23 17 Aug 2020 13:34:43

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '14:09'	(b) (4), (b) (6)	17 Aug 2020 13:34:43

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '13 Aug 2020 14:09'	System	17 Aug 2020 13:34:43

US3292158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-AUG-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample swab sample for 13-AUG-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:10:13
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-AUG-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample swab sample for 13-AUG-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' answered with 'As per source, this was collected as indicated for Visit 1 Day 1. However, after following up with PPD and onsite lab, requisition and shipping information cannot be located.' (Site from DM).	Antonio Gutierrez (b) (4)	08 Apr 2021 15:07:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-AUG-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample swab sample for 13-AUG-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number and shipped date, else, please ship the sample and provide the details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:46:36
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 13:35:04



**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '14:30'	(b) (4), (b) (6)	17 Aug 2020 13:35:04

US3292158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 13AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is missing in GCL. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).		12 Feb 2021 09:07:09
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 13AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is missing in GCL. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:24:19
User entered '13 Aug 2020 14:30'	System	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 13:35:04

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered empty.	System	17 Aug 2020 13:35:04



US3292158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:35:09

**US3292158**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	17 Aug 2020 13:35:09

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T15:59:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'fb03c69f-6c40-47fe-bba6-715a87987702'	System	13 Aug 2020 21:00:05
User entered 'Yes (Y)'	System	13 Aug 2020 21:00:05

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T15:59:42', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'fb03c69f-6c40-47fe-bba6-715a87987702'	System	13 Aug 2020 21:00:05
User entered '97.0'	System	13 Aug 2020 21:00:05

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T15:59:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'fb03c69f-6c40-47fe-bba6-715a87987702'	System	13 Aug 2020 21:00:05
User entered 'No (N)'	System	13 Aug 2020 21:00:05

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'fb03c69f-6c40-47fe-bba6-715a87987702'	System	13 Aug 2020 21:00:05
User entered '13 Aug 2020 16:00'	System	13 Aug 2020 21:00:05

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 18:06'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:21:43', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'db1f126d-1d8d-4b67-803e-7d39b599f69d'	System	14 Aug 2020 01:22:07
User entered 'Yes (Y)'	System	14 Aug 2020 01:22:07

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:21:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'db1f126d-1d8d-4b67-803e-7d39b599f69d'	System	14 Aug 2020 01:22:07
User entered '97.2'	System	14 Aug 2020 01:22:07

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:21:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'db1f126d-1d8d-4b67-803e-7d39b599f69d'	System	14 Aug 2020 01:22:07
User entered 'No (N)'	System	14 Aug 2020 01:22:07

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:04', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'db1f126d-1d8d-4b67-803e-7d39b599f69d'	System	14 Aug 2020 01:22:07
User entered '13 Aug 2020 20:22'	System	14 Aug 2020 01:22:07

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 19:01'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 2'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '59c2a088-e827-4829-b66f-4c5eba50ba9b'	System	15 Aug 2020 00:53:34
User entered 'Yes (Y)'	System	15 Aug 2020 00:53:34

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:21', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '59c2a088-e827-4829-b66f-4c5eba50ba9b'	System	15 Aug 2020 00:53:34
User entered '97.3'	System	15 Aug 2020 00:53:34

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '59c2a088-e827-4829-b66f-4c5eba50ba9b'	System	15 Aug 2020 00:53:34
User entered 'No (N)'	System	15 Aug 2020 00:53:34

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '59c2a088-e827-4829-b66f-4c5eba50ba9b'	System	15 Aug 2020 00:53:34
User entered '14 Aug 2020 19:53'	System	15 Aug 2020 00:53:34

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 3'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:01:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4193a681-6398-49a4-bf04-695f3af31823'	System	16 Aug 2020 04:02:15
User entered 'Yes (Y)'	System	16 Aug 2020 04:02:15

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4193a681-6398-49a4-bf04-695f3af31823'	System	16 Aug 2020 04:02:15
User entered '97.9'	System	16 Aug 2020 04:02:15

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:09', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4193a681-6398-49a4-bf04-695f3af31823'	System	16 Aug 2020 04:02:15
User entered 'No (N)'	System	16 Aug 2020 04:02:15

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:13', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4193a681-6398-49a4-bf04-695f3af31823'	System	16 Aug 2020 04:02:15
User entered '15 Aug 2020 23:02'	System	16 Aug 2020 04:02:15

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 4'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 5'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bd4542f6-24fa-4a87-9dd9-f662225f20a8'	System	17 Aug 2020 17:04:53
User entered 'Yes (Y)'	System	17 Aug 2020 17:04:53

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:39', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bd4542f6-24fa-4a87-9dd9-f662225f20a8'	System	17 Aug 2020 17:04:53
User entered '97.2'	System	17 Aug 2020 17:04:53

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bd4542f6-24fa-4a87-9dd9-f662225f20a8'	System	17 Aug 2020 17:04:53
User entered 'No (N)'	System	17 Aug 2020 17:04:53

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:50', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bd4542f6-24fa-4a87-9dd9-f662225f20a8'	System	17 Aug 2020 17:04:53
User entered '17 Aug 2020 12:04'	System	17 Aug 2020 17:04:53

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 6'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '64a772ad-9179-4dfe-b1c2-717001ba17e8'	System	18 Aug 2020 23:11:22
User entered 'Yes (Y)'	System	18 Aug 2020 23:11:22



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '64a772ad-9179-4dfe-b1c2-717001ba17e8' User entered '97.4'	System	18 Aug 2020 23:11:22
	System	18 Aug 2020 23:11:22

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '64a772ad-9179-4dfe-b1c2-717001ba17e8'	System	18 Aug 2020 23:11:22
User entered 'No (N)'	System	18 Aug 2020 23:11:22

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:20', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '64a772ad-9179-4dfe-b1c2-717001ba17e8'	System	18 Aug 2020 23:11:22
User entered '18 Aug 2020 18:11'	System	18 Aug 2020 23:11:22

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 7'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:39:42', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ca90cb25-196f-434d-8870-a9a114fd8fcf'	System	20 Aug 2020 05:40:02
User entered 'Yes (Y)'	System	20 Aug 2020 05:40:02

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:39:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ca90cb25-196f-434d-8870-a9a114fd8fcf'	System	20 Aug 2020 05:40:02
User entered '97.9'	System	20 Aug 2020 05:40:02



US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:39:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ca90cb25-196f-434d-8870-a9a114fd8fcf'	System	20 Aug 2020 05:40:02
User entered 'No (N)'	System	20 Aug 2020 05:40:02

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:39:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ca90cb25-196f-434d-8870-a9a114fd8fcf'	System	20 Aug 2020 05:40:02
User entered '20 Aug 2020 00:39'	System	20 Aug 2020 05:40:02

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0faae489-6728-49e1-b368-4beaf54eaf4f'	System	13 Aug 2020 21:00:38
User entered 'None (1)'	System	13 Aug 2020 21:00:38

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:15', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0faae489-6728-49e1-b368-4beaf54caf4f'	System	13 Aug 2020 21:00:38
User entered 'No (N)'	System	13 Aug 2020 21:00:38

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:21', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0faae489-6728-49e1-b368-4beaf54caf4f'	System	13 Aug 2020 21:00:38
User entered 'No (N)'	System	13 Aug 2020 21:00:38



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0faae489-6728-49e1-b368-4beaf54eaf4f'	System	13 Aug 2020 21:00:38
User entered 'None (1)'	System	13 Aug 2020 21:00:38

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0faae489-6728-49e1-b368-4beaf54eaf4f'	System	13 Aug 2020 21:00:38
User entered '13 Aug 2020 16:00'	System	13 Aug 2020 21:00:38

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 18:06'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:10', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3f1d1943-4099-4468-aab7-291c6c54fe47'	System	14 Aug 2020 01:22:30
User entered 'None (1)'	System	14 Aug 2020 01:22:30

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3f1d1943-4099-4468-aab7-291c6c54fe47'	System	14 Aug 2020 01:22:30
User entered 'No (N)'	System	14 Aug 2020 01:22:30

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3f1d1943-4099-4468-aab7-291c6c54fe47'	System	14 Aug 2020 01:22:30
User entered 'No (N)'	System	14 Aug 2020 01:22:30



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:22', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3f1d1943-4099-4468-aab7-291c6c54fe47'	System	14 Aug 2020 01:22:30
User entered 'None (1)'	System	14 Aug 2020 01:22:30

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3f1d1943-4099-4468-aab7-291c6c54fe47'	System	14 Aug 2020 01:22:30
User entered '13 Aug 2020 20:22'	System	14 Aug 2020 01:22:30

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 19:01'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 2'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:46', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '257c1e6b-8ae2-4385-b068-36a391a47a6d'	System	15 Aug 2020 00:54:12
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 00:54:12

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:53:50', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '257c1e6b-8ae2-4385-b068-36a391a47a6d'	System	15 Aug 2020 00:54:12
User entered 'No (N)'	System	15 Aug 2020 00:54:12

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '257c1e6b-8ae2-4385-b068-36a391a47a6d'	System	15 Aug 2020 00:54:12
User entered 'No (N)'	System	15 Aug 2020 00:54:12



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '257c1e6b-8ae2-4385-b068-36a391a47a6d'	System	15 Aug 2020 00:54:12
User entered 'None (1)'	System	15 Aug 2020 00:54:12

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '257c1e6b-8ae2-4385-b068-36a391a47a6d'	System	15 Aug 2020 00:54:12
User entered '14 Aug 2020 19:54'	System	15 Aug 2020 00:54:12

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 3'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:20', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a7c6923c-0bfd-469f-9757-c76672b0769e'	System	16 Aug 2020 04:02:36
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 04:02:36

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a7c6923c-0bfd-469f-9757-c76672b0769e'	System	16 Aug 2020 04:02:36
User entered 'No (N)'	System	16 Aug 2020 04:02:36

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a7c6923c-0bfd-469f-9757-c76672b0769e'	System	16 Aug 2020 04:02:36
User entered 'No (N)'	System	16 Aug 2020 04:02:36



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:29', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a7c6923c-0bfd-469f-9757-c76672b0769e'	System	16 Aug 2020 04:02:36
User entered 'None (1)'	System	16 Aug 2020 04:02:36

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a7c6923c-0bfd-469f-9757-c76672b0769e'	System	16 Aug 2020 04:02:36
User entered '15 Aug 2020 23:02'	System	16 Aug 2020 04:02:36

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 4'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 5'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd0029f27-dbc9-42d9-aa87-99a2fe713ca8'	System	17 Aug 2020 17:05:15
User entered 'None (1)'	System	17 Aug 2020 17:05:15



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:04:58', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd0029f27-dbc9-42d9-aa87-99a2fe713ca8'	System	17 Aug 2020 17:05:15
User entered 'No (N)'	System	17 Aug 2020 17:05:15

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd0029f27-dbc9-42d9-aa87-99a2fe713ca8'	System	17 Aug 2020 17:05:15
User entered 'No (N)'	System	17 Aug 2020 17:05:15

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:04', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd0029f27-dbc9-42d9-aa87-99a2fe713ca8'	System	17 Aug 2020 17:05:15
User entered 'None (1)'	System	17 Aug 2020 17:05:15

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:12', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd0029f27-dbc9-42d9-aa87-99a2fe713ca8'	System	17 Aug 2020 17:05:15
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 17:05:15

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 6'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:25', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9771aa12-f053-491f-aa57-4d9b4366f79c'	System	18 Aug 2020 23:11:43
User entered 'None (1)'	System	18 Aug 2020 23:11:43



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9771aa12-f053-491f-aa57-4d9b4366f79c'	System	18 Aug 2020 23:11:43
User entered 'No (N)'	System	18 Aug 2020 23:11:43

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9771aa12-f053-491f-aa57-4d9b4366f79c'	System	18 Aug 2020 23:11:43
User entered 'No (N)'	System	18 Aug 2020 23:11:43

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:35', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9771aa12-f053-491f-aa57-4d9b4366f79c'	System	18 Aug 2020 23:11:43
User entered 'None (1)'	System	18 Aug 2020 23:11:43

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9771aa12-f053-491f-aa57-4d9b4366f79c'	System	18 Aug 2020 23:11:43
User entered '18 Aug 2020 18:11'	System	18 Aug 2020 23:11:43

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 7'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:06', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0fb5360c-2a8c-483d-9c92-016666ad7b0c'	System	20 Aug 2020 05:40:23
User entered 'None (1)'	System	20 Aug 2020 05:40:23



US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:09', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0fb5360c-2a8c-483d-9c92-016666ad7b0c'	System	20 Aug 2020 05:40:23
User entered 'No (N)'	System	20 Aug 2020 05:40:23

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:12', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0fb5360c-2a8c-483d-9c92-016666ad7b0c'	System	20 Aug 2020 05:40:23
User entered 'No (N)'	System	20 Aug 2020 05:40:23

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:15', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0fb5360c-2a8c-483d-9c92-016666ad7b0c'	System	20 Aug 2020 05:40:23
User entered 'None (1)'	System	20 Aug 2020 05:40:23

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '0fb5360c-2a8c-483d-9c92-016666ad7b0c'	System	20 Aug 2020 05:40:23
User entered '20 Aug 2020 00:40'	System	20 Aug 2020 05:40:23

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:43', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:51', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:00:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:01:02', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:01:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'None (0)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:01:13', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered 'No (N)'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T16:01:23', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '93d94103-620e-4af3-92ee-bfd5e4d4d517'	System	13 Aug 2020 21:01:29
User entered '13 Aug 2020 16:01'	System	13 Aug 2020 21:01:29

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 18:06'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:35', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:22:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:23:02', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:23:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'None (0)'	System	14 Aug 2020 01:23:23



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:23:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered 'No (N)'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-13T20:23:20', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd555a41d-9641-4bf4-a5f8-b08da11a4e58'	System	14 Aug 2020 01:23:23
User entered '13 Aug 2020 20:23'	System	14 Aug 2020 01:23:23

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Aug 2020 19:01'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 2'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:37', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'None (0)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered 'No (N)'	System	15 Aug 2020 00:54:50

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-14T19:54:47', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd55e0b11-7747-4a8e-8c51-daa332f28fe7'	System	15 Aug 2020 00:54:50
User entered '14 Aug 2020 19:54'	System	15 Aug 2020 00:54:50

**US3292158**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:25:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 3'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:39', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:45', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:51', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'None (0)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:02:57', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered 'No (N)'	System	16 Aug 2020 04:03:09

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-15T23:03:04', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6c3131c1-4874-4076-a54b-ab03356fd32e'	System	16 Aug 2020 04:03:09
User entered '15 Aug 2020 23:03'	System	16 Aug 2020 04:03:09



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 4'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 5'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:17', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:21', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:23', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:30', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'None (0)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:35', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered 'No (N)'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-17T12:05:47', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b49840eb-fc3b-4028-99c7-a27146c28a59'	System	17 Aug 2020 17:05:53
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 17:05:53

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 20:37:32



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 6'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:45', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:51', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

**US3292158**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:25:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:11:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'None (0)'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:12:03', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered 'No (N)'	System	18 Aug 2020 23:12:19



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-18T18:12:16', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b4d53d30-8815-4811-afdf-b4e6c1cb9825'	System	18 Aug 2020 23:12:19
User entered '18 Aug 2020 18:12'	System	18 Aug 2020 23:12:19

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 7'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44



US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'None (0)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:39', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered 'No (N)'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-08-20T00:40:42', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '958012b6-5601-4509-bd4a-2dd7e45c6f1a'	System	20 Aug 2020 05:40:44
User entered '20 Aug 2020 00:40'	System	20 Aug 2020 05:40:44

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 20:37:32

US3292158

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 20:37:32

**US3292158**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 21:00:49

US3292158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Aug 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Aug 2020 21:00:49



**US3292158**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 21:00:49

US3292158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Aug 2020 21:00:49

US3292158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 22:57:47

**US3292158**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	28 Aug 2020 22:57:47

**US3292158**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 22:59:44

**US3292158**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '28 Aug 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Aug 2020 22:59:44

**US3292158**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 22:59:44

US3292158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Aug 2020 22:59:44



US3292158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Aug 2020 22:59:50

**US3292158**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	28 Aug 2020 22:59:50

**US3292158**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	07 Sep 2020 20:22:01

US3292158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 09:07:53
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DOCUMENTED' (Site from System).	Victoria Hernandez (b) (4)	24 Sep 2020 14:00:59
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Sep 2020 20:22:01
User entered '7 Sep 2020'	Kristy Trevino (b) (4)	07 Sep 2020 20:22:01

US3292158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	07 Sep 2020 20:22:01

US3292158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	07 Sep 2020 20:22:01

US3292158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	07 Sep 2020 20:28:28

**US3292158**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	07 Sep 2020 20:28:28



US3292158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:45:15

US3292158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:45:15

US3292158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[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 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:45:15

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'VISIT2'	System	12 Sep 2020 19:45:15

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12:44'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:46:12



**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '12 Sep 2020 12:44'	System	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '36.3' C	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '100'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'bpm'	System	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '16'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'breaths/min'	System	12 Sep 2020 19:46:12



US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 18:19:16
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gerardo Pena (b) (4)	12 Sep 2020 19:46:32
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Sep 2020 19:46:12
User entered '164'	Gerardo Pena (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '94'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	12 Sep 2020 19:46:12

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13:59'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02



**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '12 Sep 2020 13:59'	System	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '36.8' C	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '94'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'bpm'	System	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '16'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'breaths/min'	System	12 Sep 2020 19:48:02



US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 18:19:21
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gerardo Pena (b) (4)	12 Sep 2020 19:48:10
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Sep 2020 19:48:02
User entered '169'	Gerardo Pena (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '96'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'mmHg'	System	12 Sep 2020 19:48:02

US3292158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:25

US3292158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:25

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 18:37:24



US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13:29'	(b) (4), (b) (6)	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '12 Sep 2020 13:29'	System	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'ONCE'	System	12 Sep 2020 18:37:24

US3292158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 18:37:24



US3292158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:52

US3292158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:52

US3292158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12:55'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:48:52

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '12 Sep 2020 12:55'	System	12 Sep 2020 19:48:52

US3292158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:49:09

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:49:09

US3292158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:49:09

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '13:08'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:49:09



**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered '12 Sep 2020 13:08'	System	12 Sep 2020 19:49:09

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:49:09

US3292158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:49:09

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 19:49:09

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered empty.	System	12 Sep 2020 19:49:09

US3292158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 19:49:15

**US3292158**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'I'	System	12 Sep 2020 19:49:15

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '15b4643d-e953-4e12-aab1-271efd8f3d31'	System	12 Sep 2020 19:03:29
User entered 'Yes (Y)'	System	12 Sep 2020 19:03:29

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:13', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '15b4643d-e953-4e12-aab1-271efd8f3d31'	System	12 Sep 2020 19:03:29
User entered '98.3'	System	12 Sep 2020 19:03:29

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:17', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '15b4643d-e953-4e12-aab1-271efd8f3d31'	System	12 Sep 2020 19:03:29
User entered 'No (N)'	System	12 Sep 2020 19:03:29

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:23', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '15b4643d-e953-4e12-aab1-271efd8f3d31'	System	12 Sep 2020 19:03:29
User entered '12 Sep 2020 14:03'	System	12 Sep 2020 19:03:29

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 13:49'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 16:19'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:02', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ee9374c-1d15-478d-ad5c-841971d4178f'	System	13 Sep 2020 04:28:20
User entered 'Yes (Y)'	System	13 Sep 2020 04:28:20



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:07', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ee9374c-1d15-478d-ad5c-841971d4178f' User entered '96.8'	System	13 Sep 2020 04:28:20
	System	13 Sep 2020 04:28:20

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ee9374c-1d15-478d-ad5c-841971d4178f'	System	13 Sep 2020 04:28:20
User entered 'No (N)'	System	13 Sep 2020 04:28:20

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:15', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ee9374c-1d15-478d-ad5c-841971d4178f' User entered '12 Sep 2020 23:28'	System	13 Sep 2020 04:28:20
	System	13 Sep 2020 04:28:20

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 17:14'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 2'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:15:35', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '654e70d7-3204-433a-8d9d-a55783436023'	System	14 Sep 2020 07:15:53
User entered 'Yes (Y)'	System	14 Sep 2020 07:15:53

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:15:40', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '654e70d7-3204-433a-8d9d-a55783436023' User entered '98.2'	System	14 Sep 2020 07:15:53
	System	14 Sep 2020 07:15:53



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:15:45', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '654e70d7-3204-433a-8d9d-a55783436023'	System	14 Sep 2020 07:15:53
User entered 'No (N)'	System	14 Sep 2020 07:15:53

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:15:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '654e70d7-3204-433a-8d9d-a55783436023'	System	14 Sep 2020 07:15:53
User entered '14 Sep 2020 02:15'	System	14 Sep 2020 07:15:53

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 3'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '662799ed-2b45-4dd1-8918-07a9ea516ea4'	System	15 Sep 2020 02:51:38
User entered 'Yes (Y)'	System	15 Sep 2020 02:51:38

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '662799ed-2b45-4dd1-8918-07a9ea516ea4'	System	15 Sep 2020 02:51:38
User entered '97.4'	System	15 Sep 2020 02:51:38

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:32', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '662799ed-2b45-4dd1-8918-07a9ea516ea4'	System	15 Sep 2020 02:51:38
User entered 'No (N)'	System	15 Sep 2020 02:51:38



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '662799ed-2b45-4dd1-8918-07a9ea516ea4'	System	15 Sep 2020 02:51:38
User entered '14 Sep 2020 21:51'	System	15 Sep 2020 02:51:38

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 4'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:34:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e02060b5-09a8-4751-99b1-f1f4ac0c6fc1'	System	16 Sep 2020 04:35:06
User entered 'Yes (Y)'	System	16 Sep 2020 04:35:06

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:34:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e02060b5-09a8-4751-99b1-f1f4ac0c6fc1'	System	16 Sep 2020 04:35:06
User entered '98.4'	System	16 Sep 2020 04:35:06

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:34:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e02060b5-09a8-4751-99b1-f1f4ac0c6fc1'	System	16 Sep 2020 04:35:06
User entered 'No (N)'	System	16 Sep 2020 04:35:06

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e02060b5-09a8-4751-99b1-f1f4ac0c6fc1'	System	16 Sep 2020 04:35:06
User entered '15 Sep 2020 23:35'	System	16 Sep 2020 04:35:06



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 5'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:49:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b06632a9-0f6b-4d07-872d-c12f448c9ede'	System	16 Sep 2020 23:50:10
User entered 'Yes (Y)'	System	16 Sep 2020 23:50:10

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:49:47', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b06632a9-0f6b-4d07-872d-c12f448c9ede'	System	16 Sep 2020 23:50:10
User entered '98.0'	System	16 Sep 2020 23:50:10

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:49:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b06632a9-0f6b-4d07-872d-c12f448c9ede'	System	16 Sep 2020 23:50:10
User entered 'No (N)'	System	16 Sep 2020 23:50:10

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b06632a9-0f6b-4d07-872d-c12f448c9ede'	System	16 Sep 2020 23:50:10
User entered '16 Sep 2020 18:50'	System	16 Sep 2020 23:50:10

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 6'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:00:12', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8eb3a12f-3a99-4d28-afb8-177462f94e08'	System	18 Sep 2020 02:00:42
User entered 'Yes (Y)'	System	18 Sep 2020 02:00:42

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:00:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8eb3a12f-3a99-4d28-afb8-177462f94e08'	System	18 Sep 2020 02:00:42
User entered '98.2'	System	18 Sep 2020 02:00:42

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:00:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8eb3a12f-3a99-4d28-afb8-177462f94e08'	System	18 Sep 2020 02:00:42
User entered 'No (N)'	System	18 Sep 2020 02:00:42

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:00:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8eb3a12f-3a99-4d28-afb8-177462f94e08'	System	18 Sep 2020 02:00:42
User entered '17 Sep 2020 21:00'	System	18 Sep 2020 02:00:42

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 7'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4a373e28-a0fa-41dd-8264-63739a2c2951'	System	12 Sep 2020 19:03:58
User entered 'None (1)'	System	12 Sep 2020 19:03:58

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:39', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4a373e28-a0fa-41dd-8264-63739a2c2951'	System	12 Sep 2020 19:03:58
User entered 'No (N)'	System	12 Sep 2020 19:03:58

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:42', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4a373e28-a0fa-41dd-8264-63739a2c2951'	System	12 Sep 2020 19:03:58
User entered 'No (N)'	System	12 Sep 2020 19:03:58

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:50', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4a373e28-a0fa-41dd-8264-63739a2c2951'	System	12 Sep 2020 19:03:58
User entered 'None (1)'	System	12 Sep 2020 19:03:58

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:03:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4a373e28-a0fa-41dd-8264-63739a2c2951'	System	12 Sep 2020 19:03:58
User entered '12 Sep 2020 14:03'	System	12 Sep 2020 19:03:58

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 13:49'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 16:19'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:29', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 04:30:00

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered 'No (N)'	System	13 Sep 2020 04:30:00

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:28:38', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered 'Yes (Y)'	System	13 Sep 2020 04:30:00

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:29:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered '15'	System	13 Sep 2020 04:30:00

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:29:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered 'None (1)'	System	13 Sep 2020 04:30:00

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:29:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ffe12cae-5595-44ec-bfab-7f78ade67ef8'	System	13 Sep 2020 04:30:00
User entered '12 Sep 2020 23:29'	System	13 Sep 2020 04:30:00



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 17:14'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 2'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 07:16:34

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:04', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered 'No (N)'	System	14 Sep 2020 07:16:34

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered 'Yes (Y)'	System	14 Sep 2020 07:16:34

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered '15'	System	14 Sep 2020 07:16:34

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered 'None (1)'	System	14 Sep 2020 07:16:34



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:30', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3e6419ce-f5ab-4583-998a-c8f09e49cc6e'	System	14 Sep 2020 07:16:34
User entered '14 Sep 2020 02:16'	System	14 Sep 2020 07:16:34

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 3'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:52:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered 'No (N)'	System	15 Sep 2020 02:52:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:51:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered 'Yes (Y)'	System	15 Sep 2020 02:52:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:52:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered '5'	System	15 Sep 2020 02:52:59



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:52:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered 'None (1)'	System	15 Sep 2020 02:52:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:52:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31c1c9e7-9eea-4d59-a047-a19575247871'	System	15 Sep 2020 02:52:59
User entered '14 Sep 2020 21:52'	System	15 Sep 2020 02:52:59

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 4'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5bd785b4-6c03-4d9c-b139-b2537e579bac'	System	16 Sep 2020 04:35:29
User entered 'None (1)'	System	16 Sep 2020 04:35:29

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5bd785b4-6c03-4d9c-b139-b2537e579bac'	System	16 Sep 2020 04:35:29
User entered 'No (N)'	System	16 Sep 2020 04:35:29

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:17', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5bd785b4-6c03-4d9c-b139-b2537e579bac'	System	16 Sep 2020 04:35:29
User entered 'No (N)'	System	16 Sep 2020 04:35:29



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:20', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5bd785b4-6c03-4d9c-b139-b2537e579bac'	System	16 Sep 2020 04:35:29
User entered 'None (1)'	System	16 Sep 2020 04:35:29

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:27', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5bd785b4-6c03-4d9c-b139-b2537e579bac'	System	16 Sep 2020 04:35:29
User entered '15 Sep 2020 23:35'	System	16 Sep 2020 04:35:29

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 5'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:13', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '05ce44bd-0ef6-4014-a150-f46937e6ebb6'	System	16 Sep 2020 23:50:43
User entered 'None (1)'	System	16 Sep 2020 23:50:43

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '05ce44bd-0ef6-4014-a150-f46937e6ebb6'	System	16 Sep 2020 23:50:43
User entered 'No (N)'	System	16 Sep 2020 23:50:43

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:34', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '05ce44bd-0ef6-4014-a150-f46937e6ebb6'	System	16 Sep 2020 23:50:43
User entered 'No (N)'	System	16 Sep 2020 23:50:43



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:37', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '05ce44bd-0ef6-4014-a150-f46937e6ebb6'	System	16 Sep 2020 23:50:43
User entered 'None (1)'	System	16 Sep 2020 23:50:43

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '05ce44bd-0ef6-4014-a150-f46937e6ebb6'	System	16 Sep 2020 23:50:43
User entered '16 Sep 2020 18:50'	System	16 Sep 2020 23:50:43

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 6'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:06', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '852a8b37-b794-40bc-ad80-6293f50f7257'	System	18 Sep 2020 02:01:44
User entered 'None (1)'	System	18 Sep 2020 02:01:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:09', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '852a8b37-b794-40bc-ad80-6293f50f7257'	System	18 Sep 2020 02:01:44
User entered 'No (N)'	System	18 Sep 2020 02:01:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '852a8b37-b794-40bc-ad80-6293f50f7257'	System	18 Sep 2020 02:01:44
User entered 'No (N)'	System	18 Sep 2020 02:01:44



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '852a8b37-b794-40bc-ad80-6293f50f7257'	System	18 Sep 2020 02:01:44
User entered 'None (1)'	System	18 Sep 2020 02:01:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '852a8b37-b794-40bc-ad80-6293f50f7257'	System	18 Sep 2020 02:01:44
User entered '17 Sep 2020 21:01'	System	18 Sep 2020 02:01:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 7'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44



US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'None (0)'	System	12 Sep 2020 19:04:25



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'No interference with activity (1)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'None (0)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:12', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'None (0)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'None (0)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:17', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'None (0)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:21', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered 'No (N)'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T14:04:23', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b0833625-c6fa-4f33-b656-5e4b663e3773'	System	12 Sep 2020 19:04:25
User entered '12 Sep 2020 14:04'	System	12 Sep 2020 19:04:25

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 13:49'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 16:19'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:06', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:09', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:12', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:14', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:17', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'None (0)'	System	13 Sep 2020 04:30:28



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:21', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered 'No (N)'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-12T23:30:23', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '94b5fcc6-5421-409f-b151-504229e7eb40'	System	13 Sep 2020 04:30:28
User entered '12 Sep 2020 23:30'	System	13 Sep 2020 04:30:28

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '12 Sep 2020 17:14'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 2'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:38', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:50', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-cf06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-cf06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:16:58', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'None (0)'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:17:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered 'No (N)'	System	14 Sep 2020 07:17:05

**US3292158**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:25:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T02:17:03', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4d4550b1-ef06-4f03-8fb9-8d64486a494a'	System	14 Sep 2020 07:17:05
User entered '14 Sep 2020 02:17'	System	14 Sep 2020 07:17:05

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 3'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:01', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'None (0)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:07', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:10', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'None (0)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:15', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'None (0)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'None (0)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:22', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'None (0)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:26', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered 'No (N)'	System	15 Sep 2020 02:53:32

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-14T21:53:29', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e1a9fe32-a8a2-4606-be7e-7f2baa67702f'	System	15 Sep 2020 02:53:32
User entered '14 Sep 2020 21:53'	System	15 Sep 2020 02:53:32



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 4'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:36', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:39', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:45', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:51', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'None (0)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:54', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered 'No (N)'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-15T23:35:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '6bca5db3-2cb8-4f52-9542-c1e1c24569e0'	System	16 Sep 2020 04:36:01
User entered '15 Sep 2020 23:35'	System	16 Sep 2020 04:36:01

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 5'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:56', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:50:58', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:03', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:06', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'None (0)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:10', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered 'No (N)'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-16T18:51:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '947f9ad2-1b2c-43ec-bca1-13afd160661a'	System	16 Sep 2020 23:51:22
User entered '16 Sep 2020 18:51'	System	16 Sep 2020 23:51:22

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 18:37:24



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 6'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:33', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:43', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:01:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:02:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'None (0)'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:02:15', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered 'No (N)'	System	18 Sep 2020 02:02:43



US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-09-17T21:02:25', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a36d9379-b039-41ca-b7aa-e63d907b17fd'	System	18 Sep 2020 02:02:43
User entered '17 Sep 2020 21:02'	System	18 Sep 2020 02:02:43

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	12 Sep 2020 18:37:24
User entered 'Day 7'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44



**US3292158**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:25:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 18:37:24

US3292158

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:25:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 18:37:24

**US3292158**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 22:29:51

**US3292158**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Sep 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Sep 2020 22:29:51



US3292158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 22:29:51

US3292158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Sep 2020 22:29:51

US3292158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Sep 2020 22:29:56

**US3292158**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	21 Sep 2020 22:29:56

**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:05:00

**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 18:05:00

**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 18:05:00

**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:05:00



**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:05:05

**US3292158**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	28 Sep 2020 18:05:05

**US3292158**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:45:20

**US3292158**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 19:45:20

**US3292158**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 19:45:20

**US3292158**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:45:20

US3292158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:45:24

**US3292158**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	05 Oct 2020 19:45:24



**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:50

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:50

US3292158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[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 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:50

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered 'VISIT3'	System	08 Oct 2020 21:09:50

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '14:02'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered '8 Oct 2020 14:02'	System	08 Oct 2020 21:10:41



US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '36.3' C	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '98'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered 'bpm'	System	08 Oct 2020 21:10:41

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered 'breaths/min'	System	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '152'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41



**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered 'mmHg'	System	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '74'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:10:41

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered 'mmHg'	System	08 Oct 2020 21:10:41

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31

US3292158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31

US3292158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:43

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:25:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 21:09:43

US3292158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:33



US3292158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 21:09:33

US3292158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '14:09'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:33

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:31
User entered '8 Oct 2020 14:09'	System	08 Oct 2020 21:09:33

US3292158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 21:09:37

**US3292158**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'I'	System	08 Oct 2020 21:09:37

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 64'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 20:37:32



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:31:15
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 71'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-20T12:17:40', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5d12cb39-60e0-46f1-8f66-d55c67d42dfa'	System	20 Oct 2020 17:18:08
User entered 'No (N)'	System	20 Oct 2020 17:18:08

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-20T12:17:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5d12cb39-60e0-46f1-8f66-d55c67d42dfa'	System	20 Oct 2020 17:18:08
User entered 'No (N)'	System	20 Oct 2020 17:18:08

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-20T12:18:04', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5d12cb39-60e0-46f1-8f66-d55c67d42dfa'	System	20 Oct 2020 17:18:08
User entered '20 Oct 2020 12:18:04'	System	20 Oct 2020 17:18:08

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 20:37:32

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 78'	System	13 Aug 2020 20:37:32



US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-30T13:51:48', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '34beffbb-abe5-41d0-a365-4a9090feed2f'	System	30 Oct 2020 18:52:10
User entered 'No (N)'	System	30 Oct 2020 18:52:10

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-30T13:52:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '34beffbb-abe5-41d0-a365-4a9090feed2f'	System	30 Oct 2020 18:52:10
User entered 'No (N)'	System	30 Oct 2020 18:52:10

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-10-30T13:52:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '34beffbb-abe5-41d0-a365-4a9090feed2f' User entered '30 Oct 2020 13:52:05'	System	30 Oct 2020 18:52:10
	System	30 Oct 2020 18:52:10

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 20:37:32

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 92'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-10T13:36:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '841c184f-1df8-4633-8b42-b6eebb691494'	System	10 Nov 2020 19:37:58
User entered 'No (N)'	System	10 Nov 2020 19:37:58

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-10T13:37:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '841c184f-1df8-4633-8b42-b6eebb691494'	System	10 Nov 2020 19:37:58
User entered 'No (N)'	System	10 Nov 2020 19:37:58



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-10T13:37:54', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '841c184f-1df8-4633-8b42-b6eebb691494'	System	10 Nov 2020 19:37:58
User entered '10 Nov 2020 13:37:54'	System	10 Nov 2020 19:37:58

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 20:37:32

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered 'Day 99'	System	13 Aug 2020 20:37:32

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-17T22:05:20', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8987ce27-2456-406d-b41c-84878485a5fb'	System	18 Nov 2020 04:05:40
User entered 'No (N)'	System	18 Nov 2020 04:05:40

US3292158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-17T22:05:32', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8987ce27-2456-406d-b41c-84878485a5fb'	System	18 Nov 2020 04:05:40
User entered 'No (N)'	System	18 Nov 2020 04:05:40

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-17T22:05:35', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8987ce27-2456-406d-b41c-84878485a5fb'	System	18 Nov 2020 04:05:40
User entered '17 Nov 2020 22:05:35'	System	18 Nov 2020 04:05:40

**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 20:37:32



**US3292158**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:58:44
Data entry locked.	System	13 Aug 2020 20:37:32
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 20:37:32

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-22T19:53:43', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e55ffe40-25be-47c0-94d8-c451436a7ce4'	System	23 Nov 2020 01:54:06
User entered 'No (N)'	System	23 Nov 2020 01:54:06

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-22T19:53:58', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e55ffe40-25be-47c0-94d8-c451436a7ce4'	System	23 Nov 2020 01:54:06
User entered 'No (N)'	System	23 Nov 2020 01:54:06

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-22T19:54:02', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'e55ffe40-25be-47c0-94d8-c451436a7ce4'	System	23 Nov 2020 01:54:06
User entered '22 Nov 2020 19:54:02'	System	23 Nov 2020 01:54:06

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-28T18:26:50', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bcb08c41-b5bf-4539-8234-9a4be4f4fb72'	System	29 Nov 2020 00:27:11
User entered 'No (N)'	System	29 Nov 2020 00:27:11

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-28T18:27:05', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bcb08c41-b5bf-4539-8234-9a4be4f4fb72'	System	29 Nov 2020 00:27:11
User entered 'No (N)'	System	29 Nov 2020 00:27:11

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-11-28T18:27:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'bcb08c41-b5bf-4539-8234-9a4be4f4fb72'	System	29 Nov 2020 00:27:11
User entered '28 Nov 2020 18:27:08'	System	29 Nov 2020 00:27:11

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-05T01:24:03', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3d3301b9-b910-4481-9961-d700ab4d3d10'	System	05 Dec 2020 07:24:12
User entered 'No (N)'	System	05 Dec 2020 07:24:12

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-05T01:24:07', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3d3301b9-b910-4481-9961-d700ab4d3d10'	System	05 Dec 2020 07:24:12
User entered 'No (N)'	System	05 Dec 2020 07:24:12



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-05T01:24:11', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3d3301b9-b910-4481-9961-d700ab4d3d10'	System	05 Dec 2020 07:24:12
User entered '05 Dec 2020 01:24:11'	System	05 Dec 2020 07:24:12

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-15T14:46:40', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3a3fa002-904b-40ab-bbb7-347b0ea4488c'	System	15 Dec 2020 20:46:49
User entered 'No (N)'	System	15 Dec 2020 20:46:49

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-15T14:46:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3a3fa002-904b-40ab-bbb7-347b0ea4488c'	System	15 Dec 2020 20:46:49
User entered 'No (N)'	System	15 Dec 2020 20:46:49

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-15T14:46:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3a3fa002-904b-40ab-bbb7-347b0ea4488c' User entered '15 Dec 2020 14:46:44'	System	15 Dec 2020 20:46:49
	System	15 Dec 2020 20:46:49

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-20T15:24:29', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a3f2ba85-1239-4007-8f35-24f8f145aabf'	System	20 Dec 2020 21:24:39
User entered 'No (N)'	System	20 Dec 2020 21:24:39

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-20T15:24:32', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a3f2ba85-1239-4007-8f35-24f8f145aabf'	System	20 Dec 2020 21:24:39
User entered 'No (N)'	System	20 Dec 2020 21:24:39

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-20T15:24:37', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'a3f2ba85-1239-4007-8f35-24f8f145aabf' User entered '20 Dec 2020 15:24:37'	System	20 Dec 2020 21:24:39
	System	20 Dec 2020 21:24:39

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-27T22:04:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '57d3e613-0b14-4f41-86cb-4cbda41329df'	System	28 Dec 2020 04:05:00
User entered 'No (N)'	System	28 Dec 2020 04:05:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-27T22:04:54', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '57d3e613-0b14-4f41-86cb-4cbda41329df'	System	28 Dec 2020 04:05:00
User entered 'No (N)'	System	28 Dec 2020 04:05:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2020-12-27T22:04:57', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '57d3e613-0b14-4f41-86cb-4cbda41329df' User entered '27 Dec 2020 22:04:57'	System	28 Dec 2020 04:05:00
	System	28 Dec 2020 04:05:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-06T14:55:24', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9a5bb50a-7093-40e0-8ef5-f533eed76e15'	System	06 Jan 2021 20:55:35
User entered 'No (N)'	System	06 Jan 2021 20:55:35

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-06T14:55:30', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9a5bb50a-7093-40e0-8ef5-f533eed76e15'	System	06 Jan 2021 20:55:35
User entered 'No (N)'	System	06 Jan 2021 20:55:35



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-06T14:55:33', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '9a5bb50a-7093-40e0-8ef5-f533eed76e15' User entered '06 Jan 2021 14:55:33'	System	06 Jan 2021 20:55:35
	System	06 Jan 2021 20:55:35

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-10T09:45:47', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8747fc90-b553-4340-8e3c-feedec7439e5'	System	10 Jan 2021 16:46:00
User entered 'No (N)'	System	10 Jan 2021 16:46:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-10T09:45:49', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8747fc90-b553-4340-8e3c-feedec7439e5'	System	10 Jan 2021 16:46:00
User entered 'No (N)'	System	10 Jan 2021 16:46:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-10T09:45:53', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '8747fc90-b553-4340-8e3c-feedec7439e5' User entered '10 Jan 2021 09:45:53'	System	10 Jan 2021 16:46:00
	System	10 Jan 2021 16:46:00

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-16T11:07:31', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ad6850ab-4934-4937-9a8a-ec91898c2561'	System	16 Jan 2021 18:07:46
User entered 'No (N)'	System	16 Jan 2021 18:07:46

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-16T11:07:41', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ad6850ab-4934-4937-9a8a-ec91898c2561'	System	16 Jan 2021 18:07:46
User entered 'No (N)'	System	16 Jan 2021 18:07:46

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-16T11:07:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'ad6850ab-4934-4937-9a8a-ec91898c2561' User entered '16 Jan 2021 11:07:44'	System	16 Jan 2021 18:07:46
	System	16 Jan 2021 18:07:46

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-23T18:39:18', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3ab6d52e-ca1b-4778-9698-8854334c25a3'	System	24 Jan 2021 00:39:33
User entered 'No (N)'	System	24 Jan 2021 00:39:33

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-23T18:39:28', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3ab6d52e-ca1b-4778-9698-8854334c25a3'	System	24 Jan 2021 00:39:33
User entered 'No (N)'	System	24 Jan 2021 00:39:33

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-23T18:39:30', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3ab6d52e-ca1b-4778-9698-8854334c25a3' User entered '23 Jan 2021 18:39:30'	System	24 Jan 2021 00:39:33

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-30T15:24:43', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ae78fc0-7cc2-4456-b521-5e2c662d8d84'	System	30 Jan 2021 21:24:58
User entered 'No (N)'	System	30 Jan 2021 21:24:58

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-30T15:24:52', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ae78fc0-7cc2-4456-b521-5e2c662d8d84'	System	30 Jan 2021 21:24:58
User entered 'No (N)'	System	30 Jan 2021 21:24:58



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-01-30T15:24:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '5ae78fc0-7cc2-4456-b521-5e2c662d8d84' User entered '30 Jan 2021 15:24:55'	System	30 Jan 2021 21:24:58
	System	30 Jan 2021 21:24:58

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-06T19:28:16', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3113823a-24d9-4f92-bab9-4653d27456b5'	System	07 Feb 2021 01:28:24
User entered 'No (N)'	System	07 Feb 2021 01:28:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-06T19:28:19', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3113823a-24d9-4f92-bab9-4653d27456b5'	System	07 Feb 2021 01:28:24
User entered 'No (N)'	System	07 Feb 2021 01:28:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-06T19:28:22', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '3113823a-24d9-4f92-bab9-4653d27456b5'	System	07 Feb 2021 01:28:24
User entered '06 Feb 2021 19:28:22'	System	07 Feb 2021 01:28:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-13T17:06:55', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '45ebe5dc-bb44-436f-baed-62df53376487'	System	13 Feb 2021 23:12:19
User entered 'No (N)'	System	13 Feb 2021 23:12:19

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-13T17:06:57', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '45ebe5dc-bb44-436f-baed-62df53376487'	System	13 Feb 2021 23:12:19
User entered 'No (N)'	System	13 Feb 2021 23:12:19

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-13T17:06:59', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '45ebe5dc-bb44-436f-baed-62df53376487' User entered '13 Feb 2021 17:06:59'	System	13 Feb 2021 23:12:19
	System	13 Feb 2021 23:12:19

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-20T19:04:44', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '2ce4ae7b-9710-4563-b473-a5a09f6d28d8'	System	21 Feb 2021 01:05:10
User entered 'No (N)'	System	21 Feb 2021 01:05:10

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-20T19:05:06', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '2ce4ae7b-9710-4563-b473-a5a09f6d28d8'	System	21 Feb 2021 01:05:10
User entered 'No (N)'	System	21 Feb 2021 01:05:10

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-20T19:05:08', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '2ce4ae7b-9710-4563-b473-a5a09f6d28d8'	System	21 Feb 2021 01:05:10
User entered '20 Feb 2021 19:05:08'	System	21 Feb 2021 01:05:10

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-27T16:33:22-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'cdb39dc0-9f96-4600-8dde-4a4cc7537c93'	System	27 Feb 2021 22:33:32
User entered 'No (N)'	System	27 Feb 2021 22:33:32

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-27T16:33:25-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'cdb39dc0-9f96-4600-8dde-4a4cc7537c93'	System	27 Feb 2021 22:33:32
User entered 'No (N)'	System	27 Feb 2021 22:33:32



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-27T16:33:28-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'cdb39dc0-9f96-4600-8dde-4a4cc7537c93'	System	27 Feb 2021 22:33:32
User entered '27 Feb 2021 16:33:28'	System	27 Feb 2021 22:33:32

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-06T16:53:06-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd5de7aae-206e-46b1-8b81-f4400f0ba283' User entered 'No (N)'	System	06 Mar 2021 22:53:15
	System	06 Mar 2021 22:53:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-06T16:53:10-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd5de7aae-206e-46b1-8b81-f4400f0ba283'	System	06 Mar 2021 22:53:15
User entered 'No (N)'	System	06 Mar 2021 22:53:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-06T16:53:13-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'd5de7aae-206e-46b1-8b81-f4400f0ba283' User entered '06 Mar 2021 16:53:13'	System	06 Mar 2021 22:53:15
	System	06 Mar 2021 22:53:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-20T14:44:56-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '89671291-a15e-43d1-9427-175165be3064'	System	20 Mar 2021 19:45:14
User entered 'No (N)'	System	20 Mar 2021 19:45:14

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-20T14:45:05-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '89671291-a15e-43d1-9427-175165be3064'	System	20 Mar 2021 19:45:14
User entered 'No (N)'	System	20 Mar 2021 19:45:14

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-20T14:45:09-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '89671291-a15e-43d1-9427-175165be3064'	System	20 Mar 2021 19:45:14
User entered '20 Mar 2021 14:45:09'	System	20 Mar 2021 19:45:14



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:03-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered 'Yes (Y)'	System	28 Mar 2021 17:08:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:10-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered 'No (N)'	System	28 Mar 2021 17:08:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:14-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered 'No (N)'	System	28 Mar 2021 17:08:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:23-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered 'Yes (Y)'	System	28 Mar 2021 17:08:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:30-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 17:08:24



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-03-28T12:06:33-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'b5dd6654-433a-4492-957c-5c35f43ad095'	System	28 Mar 2021 17:08:24
User entered '28 Mar 2021 12:06:33'	System	28 Mar 2021 17:08:24

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:55:57-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f'	System	03 Apr 2021 23:56:37
User entered 'Yes (Y)'	System	03 Apr 2021 23:56:37

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:56:03-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f'	System	03 Apr 2021 23:56:37
User entered 'No (N)'	System	03 Apr 2021 23:56:37

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:56:12-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f'	System	03 Apr 2021 23:56:37
User entered 'No (N)'	System	03 Apr 2021 23:56:37

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:56:17-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f'	System	03 Apr 2021 23:56:37
User entered 'Yes (Y)'	System	03 Apr 2021 23:56:37



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:56:22-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f'	System	03 Apr 2021 23:56:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 23:56:37

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-03T16:56:25-07:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'dda1724f-f90e-4a16-b831-12d9dc30328f' User entered '03 Apr 2021 16:56:25'	System	03 Apr 2021 23:56:37
	System	03 Apr 2021 23:56:37

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:42-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered 'Yes (Y)'	System	12 Apr 2021 21:07:20

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:45-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered 'No (N)'	System	12 Apr 2021 21:07:20

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:49-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered 'No (N)'	System	12 Apr 2021 21:07:20



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:54-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered 'Yes (Y)'	System	12 Apr 2021 21:07:20

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:57-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Apr 2021 21:07:20

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-12T16:06:59-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '31f3dd0b-a252-4c83-ae7b-45ca04898322'	System	12 Apr 2021 21:07:20
User entered '12 Apr 2021 16:06:59'	System	12 Apr 2021 21:07:20

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-18T16:10:28-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '96179bb3-813e-4295-bdee-a21baf5b2efd' User entered 'No (N)'	System	18 Apr 2021 21:10:39
	System	18 Apr 2021 21:10:39

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-18T16:10:30-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '96179bb3-813e-4295-bdee-a21baf5b2efd' User entered 'No (N)'	System	18 Apr 2021 21:10:39



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-18T16:10:33-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '96179bb3-813e-4295-bdee-a21baf5b2efd' User entered '18 Apr 2021 16:10:33'	System	18 Apr 2021 21:10:39
	System	18 Apr 2021 21:10:39

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-24T14:30:20-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'f3aea9ce-c301-4005-8ed9-01bec846b576'	System	24 Apr 2021 19:30:31
User entered 'No (N)'	System	24 Apr 2021 19:30:31

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-24T14:30:23-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'f3aea9ce-c301-4005-8ed9-01bec846b576'	System	24 Apr 2021 19:30:31
User entered 'No (N)'	System	24 Apr 2021 19:30:31

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-04-24T14:30:26-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: 'f3aea9ce-c301-4005-8ed9-01bec846b576'	System	24 Apr 2021 19:30:31
User entered '24 Apr 2021 14:30:26'	System	24 Apr 2021 19:30:31

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-05-02T15:45:35-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '248ca3b8-7571-46f3-bbb0-4b0ba48177ac' User entered 'No (N)'	System	02 May 2021 20:45:48
	System	02 May 2021 20:45:48

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-05-02T15:45:39-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '248ca3b8-7571-46f3-bbb0-4b0ba48177ac'	System	02 May 2021 20:45:48
User entered 'No (N)'	System	02 May 2021 20:45:48

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-05-02T15:45:42-05:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '248ca3b8-7571-46f3-bbb0-4b0ba48177ac' User entered '02 May 2021 15:45:42'	System	02 May 2021 20:45:48
	System	02 May 2021 20:45:48

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:31:15



**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:31:15

**US3292158**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:25:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:31:15
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:31:15

US3292158

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:25:42**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-27T16:33:38-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4e0b68ba-aefd-4a21-bf23-4e518033d579'	System	27 Feb 2021 22:33:44
User entered 'No (N)'	System	27 Feb 2021 22:33:44

**US3292158**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:31:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46ae2ac6e01cbd1b)', Time: '2021-02-27T16:33:42-06:00', User OID: 'PatientReportedOutcome (US3292158)', ODM File OID: '4e0b68ba-aefd-4a21-bf23-4e518033d579' User entered '27 Feb 2021 16:33:42'	System	27 Feb 2021 22:33:44
	System	27 Feb 2021 22:33:44

**US3292158**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:17:05

**US3292158**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 21:17:05

**US3292158**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 21:17:05



US3292158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:05

**US3292158**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:17:17

**US3292158**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:40:30
User entered 'l'	System	09 Nov 2020 21:17:17

**US3292158**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 17:23:53

**US3292158**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '11 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	14 Dec 2020 17:23:53

**US3292158**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 17:23:53

US3292158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	14 Dec 2020 17:23:53

US3292158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Dec 2020 17:23:56



**US3292158**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User entered 'l'	System	14 Dec 2020 17:23:56

**US3292158**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Jan 2021 19:33:40

**US3292158**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '12 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	14 Jan 2021 19:33:40

**US3292158**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	14 Jan 2021 19:33:40

US3292158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	14 Jan 2021 19:33:40

US3292158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Jan 2021 19:33:43

**US3292158**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User entered 'l'	System	14 Jan 2021 19:33:43

**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 20:12:05



**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '9 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 20:12:05

**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Feb 2021 20:12:05

**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 20:12:05

**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 20:12:11

**US3292158**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:24:07
User entered 'l'	System	10 Feb 2021 20:12:11

US3292158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:16

US3292158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered '12 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:16

US3292158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:16



US3292158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'VISIT4'	System	15 Mar 2021 21:52:16

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

**US3292158**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:25:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12



US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:07
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:29:12

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered empty.	System	31 Mar 2021 19:29:12



US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37

US3292158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37

US3292158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:20

US3292158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:20

US3292158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:30

US3292158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '12 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:30

US3292158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '14:50'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:30

**US3292158**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:25:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered '12 Mar 2021 14:50'	System	15 Mar 2021 21:52:30



US3292158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:52:33

**US3292158**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:36:37
User entered 'I'	System	15 Mar 2021 21:52:33

**US3292158**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:34:13

US3292158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:34:13

**US3292158**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:25:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:34:13

US3292158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:34:13

US3292158

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:34:16

**US3292158**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:25:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 13:34:16



**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:29:28

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:29:28

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:29:28

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:25:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 17:29:28

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:29:43

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:25:42**

[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 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:53:38

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:25:42**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:25:42**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:53:38



US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:25:42**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:25:42**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:29:43

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User entered empty.	System	22 Jan 2021 17:29:43

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User entered empty.	System	22 Jan 2021 17:29:43

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:29:58



US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 17:29:58

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '15:07'	(b) (4), (b) (6)	22 Jan 2021 17:29:58

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User entered '21 Jan 2021 15:07'	System	22 Jan 2021 17:29:58

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:25:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:30:08

US3292158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 17:30:08

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:25:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '15:16'	(b) (4), (b) (6)	22 Jan 2021 17:30:08

**US3292158**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:25:42**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:13
User entered '21 Jan 2021 15:16'	System	22 Jan 2021 17:30:08

US3292158

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:25:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:33
DataPoint Verified.	(b) (4)	30 Apr 2021 21:50:35
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Signature has been broken.	(b) (4)	
	Antonio Gutierrez (b) (4)	29 Mar 2021 21:35:48
User entered 'Yes (Y)' reason for change: New Information	Antonio Gutierrez (b) (4)	29 Mar 2021 21:35:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
	(b) (4)	
User entered 'No (N)'	Dawn Killian (b) (4)	03 Feb 2021 22:11:42
	(b) (4)	



**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:36:27
Reviewed for Safety.		30 Mar 2021 13:29:46
User entered 'USA-US072-2021-mRNA-1273-P301000019'	System	30 Mar 2021 13:29:38
User entered 'New'	(b) (4), (b) (6)	30 Mar 2021 13:29:38

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:36:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 22:28:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 22:28:10
Data point term sent to Coder	System	29 Mar 2021 21:51:05
User entered 'Exacerbation of COPD'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:36:48
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:36:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:36:53
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:37:01
User entered '26 Mar 2021'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:37:07
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:50:19



**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:49:10
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	20 Apr 2021 14:56:44
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:49:12
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).		21 Apr 2021 18:49:19
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	20 Apr 2021 14:58:37
User entered '29 Mar 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	20 Apr 2021 14:56:44
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 11:42:12
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:49:14
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:38:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:38:58
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:38:59
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:01
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19



US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 09:15:01
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient not admitted to ICU. Patient not yet discharged.' (Site from System).	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:49
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	29 Mar 2021 21:50:19
User entered 'I'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:08:30
User entered '28 Mar 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	20 Apr 2021 14:56:44
User entered '27 Mar 2021'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:55:42
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).		21 Apr 2021 18:49:22
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	20 Apr 2021 14:58:44
User entered '29 Mar 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	20 Apr 2021 14:56:44
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 11:41:58
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:07
User entered 'No (N)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:08
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:10
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:11
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:12
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19



**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:27
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:29
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:39:30
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:55:48
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:48:00
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 Apr 2021 17:03:47
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 'Conmed log updated' (Site from Safety).	Nathan Cortez (b) (4)	26 Apr 2021 21:17:30
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)	06 Apr 2021 11:42:43
User entered 'I'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:08:37
User entered '0'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:56:04
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).		21 Apr 2021 18:49:25
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	20 Apr 2021 14:58:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Antonio Gutierrez (b) (4)	20 Apr 2021 14:56:44
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 11:42:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:56:07
User entered empty.	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19



US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:04:12
	(b) (4), (b) (6)	30 Apr 2021 14:56:33
User closed query 'Per DM CLR: Narrative indicates that subject had "STEROIDS AND ANTIBIOTIC." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 09:39:21
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 'Lab results scanned and emailed' (Site from Safety).	Nathan Cortez (b) (4)	26 Apr 2021 21:28:36
Query 'Per DM CLR: Narrative indicates that subject had "STEROIDS AND ANTIBIOTIC." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Cmed log updated per discharge summary' (Site from DM).	Nathan Cortez (b) (4)	26 Apr 2021 21:18:41
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 18:49:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'none noted in d/c paperwork' (Site from Safety).	Antonio Gutierrez (b) (4)	20 Apr 2021 15:00:10

US3292158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 11:42:54
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		06 Apr 2021 11:41:44
User opened query 'Per DM CLR: Narrative indicates that subject had "STEROIDS AND ANTIBIOTIC." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		03 Apr 2021 10:57:02
User entered 'SUBJECT ANSWERED "YES" IN EDIARY ON 28MAR2021 TO QUESTION ABOUT SEEING A HEALTHCARE PROVIDER. UPON CONTACTING SUBJECT, HE STATED THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 27MAR2021 DUE TO EXACERBATION OF COPD STARTING ON 26MAR2021--UNABLE TO BREATHE EASILY. SUBJECT WAS ADMITTED TO THE VA HOSPITAL AND HAS RECEIVED STEROIDS AND ANTIBIOTICS. SUBJECT UNABLE TO NAME THOSE MEDICATIONS AT THIS TIME. AS OF 29MAR21, SUBJECT STATES HE EXPECTS TO BE DISCHARGED THIS EVENING, BUT IS STILL ADMITTED AS OF LAST CONVERSATION. Patient was also asked if anything in particular made his condition worse, to which the patient replied, "South Texas allergy season". MEDICAL RECORDS WILL BE REQUESTED AS SOON AS POSSIBLE AND THIS REPORT WILL BE UPDATED.' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	29 Mar 2021 21:55:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject answered "yes" in eDiary on 28Mar2021 to question about seeing a healthcare provider. Upon contacting subject, he stated that he had been admitted to the hospital on 27Mar2021 due to exacerbation of COPD starting on 26Mar2021--unable to breathe easily. Subject was admitted to the VA hospital and has received steroids and antibiotics. Subject unable to name those medications at this time. As of 29MAR21, subject states he expects to be discharged this evening, but is still admitted as of last conversation. Medical records will be requested as soon as possible and this report will be updated.'	Antonio Gutierrez (b) (4)	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 21:50:19

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 15:21:44
DataPoint Verified.		29 Apr 2021 20:41:10
User entered 'USA-US072-2021-mRNA-1273-P301000019'		08 Apr 2021 20:05:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 15:21:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 15:21:41
Data point term sent to Coder	System	08 Apr 2021 15:19:55
User entered 'Exacerbation of COPD'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08



**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:13
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:15
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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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)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:17
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:19
User entered '7 Apr 2021'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:20
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 15:19:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome for the second event of exacerbation of COPD, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:22:47
User closed query 'PV Query: Please provide the event end date for the second event of exacerbation of COPD, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).		03 May 2021 15:21:50
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:50:55
Query 'PV Query: Please provide the event end date for the second event of exacerbation of COPD, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'Date updated per patient report. Records requested again, we will update data if records do not reflect patient report.' (Site from Safety).	Nathan Cortez (b) (4)	30 Apr 2021 21:43:54
Query 'PV Query: Please provide the final event outcome for the second event of exacerbation of COPD, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Date updated per patient report. Records requested again, we will update data if records do not reflect patient report.' (Site from Safety).	Nathan Cortez (b) (4)	30 Apr 2021 21:43:50
DataPoint Un-verified.	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:58:01
User opened query 'PV Query: Please provide the final event outcome for the second event of exacerbation of COPD, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:15:34
User opened query 'PV Query: Please provide the event end date for the second event of exacerbation of COPD, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).		29 Apr 2021 13:15:20
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08



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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 10:07:38
	(b) (4), (b) (6)	30 Apr 2021 21:50:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Date updated per patient report. Records requested again, we will update data if records do not reflect patient report.' (Site from System).	Nathan Cortez (b) (4)	30 Apr 2021 21:43:46
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	30 Apr 2021 21:42:41
	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41
User entered '09 Apr 2021' reason for change: Data Entry Error DataPoint Verified.	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41
	(b) (4), (b) (6)	30 Apr 2021 14:58:03
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:41:35
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:05
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:09
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:16
User opened query 'Per CDM: Response noted 'Not in ICU and not discharged yet'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).		09 Apr 2021 12:57:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		09 Apr 2021 12:57:08
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Not in ICU and not discharged yet' (Site from System).	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:26
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 Apr 2021 15:19:08
User entered 'I'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:47
User entered '7 Apr 2021'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date for the second event of exacerbation of COPD when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:22:44
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:05
Query 'PV Query: Please provide the hospital discharge date for the second event of exacerbation of COPD when available.' answered with 'Date updated per patient report. Records requested again, we will update data if records do not reflect patient report.' (Site from Safety).	Nathan Cortez (b) (4)	30 Apr 2021 21:43:40
DataPoint Un-verified.	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41
User entered '09 Apr 2021' reason for change: Data Entry Error	Nathan Cortez (b) (4)	30 Apr 2021 21:42:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:03:29
User opened query 'PV Query: Please provide the hospital discharge date for the second event of exacerbation of COPD when available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:14:42
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:54
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:56
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:42:57
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered 'l'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered '0'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:43:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:10:36
User entered empty.	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08

US3292158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject has a history of smoking or is a current smoker. If so, please update the medical history. Smoking cessation resources was noted in the discharge summary. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:22:40
Query 'PV Query: Please confirm if the subject has a history of smoking or is a current smoker. If so, please update the medical history. Smoking cessation resources was noted in the discharge summary. ' answered with 'Confirmed patient does have hx of smoking. To be added to Med Hx once form is unlocked.' (Site from Safety).	Nathan Cortez (b) (4)	30 Apr 2021 17:52:00
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:58:50
User opened query 'PV Query: Please confirm if the subject has a history of smoking or is a current smoker. If so, please update the medical history. Smoking cessation resources was noted in the discharge summary. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:14:24
User entered 'Called patient 08APR21 to follow up on previous SAE. Patient states he has been hospitalized once again for the same condition. States on the evening of 07APR21, he was unable to breathe comfortably or catch his breath. Presented to ER and was admitted. No further information available at this time.'	Antonio Gutierrez (b) (4)	08 Apr 2021 15:19:08



**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 15:19:08

**US3292158**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 15:19:08

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:25:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:33
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 13:36:38

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 00:32:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:32:17
Data point term sent to Coder	System	17 Aug 2020 13:39:23
User entered 'fluticasone'	(b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Rhinorrhea'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '50'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'nasal'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:25
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:39:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:39:04
User entered 'un UNK 2015'	(b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04



**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:39:04

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:39:04

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:39:04

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 22:03:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 22:03:41
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4)	24 Sep 2020 14:06:04 24 Sep 2020 14:06:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 13:42:21
Data point term sent to Coder User entered 'Furosemide'	System (b) (4), (b) (6)	17 Aug 2020 13:41:26 17 Aug 2020 13:41:00

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please update the indication to reflect the location of EDEMA (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:27:37
Query 'Per DM CLR: Please update the indication to reflect the location of EDEMA (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH eCRF as appropriate. ' answered with 'DOCUMENTED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 14:06:10
User entered 'GENERALIZED EDEMA' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:06:03
User opened query 'Per DM CLR: Please update the indication to reflect the location of EDEMA (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:33:17
User entered 'Edema'	(b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '20'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:31
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:41:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:41:00
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:41:00

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:41:00

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:41:00



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:43:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 13:43:13
Data point term sent to Coder	System	17 Aug 2020 13:42:29
User entered 'Metformin'	(b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Type II Diabetes'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '500'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:10:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medicationis ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:41:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:41:43
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:41:43

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:41:43



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:41:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:41:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:46:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 13:46:22
Data point term sent to Coder	System	17 Aug 2020 13:45:42
User entered 'mirtazapine'	(b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'depression'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '15'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:40
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:45:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:45:17
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:45:17

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:45:17

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:45:17

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:45:17

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 01:05:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 01:05:16
Data point term sent to Coder	System	17 Aug 2020 13:46:47
User entered 'montelukast'	(b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Rhinorrhea'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '10'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:43
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:47:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:46:16
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16



**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:46:16

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:46:16

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: NICOTINIC ACID AND DERIVATIVES, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 11:33:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:33:46
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4)	24 Sep 2020 14:11:16 24 Sep 2020 14:10:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: NICOTINIC ACID AND DERIVATIVES, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 11:38:56
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 Aug 2020 11:38:56
Data point term sent to Coder User entered 'Niacin'	System (b) (4), (b) (6)	17 Aug 2020 13:48:51 17 Aug 2020 13:48:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:56:28
Query 'Per MM, Please revise the indication ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:11:02
User entered 'HYPERTENSION' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:10:47
User opened query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:54:16
User entered 'Rhinorrhea'		17 Aug 2020 13:48:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR-Requery: Response noted. However, dose unit MG is still not recorded in the dose unit section. Please update dose and dose unit as appropriate. Also, kindly refrain from recording as updated in the comment box if it still not reconciled.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 11:01:33
Query 'Per DM CLR-Requery: Response noted. However, dose unit MG is still not recorded in the dose unit section. Please update dose and dose unit as appropriate. Also, kindly refrain from recording as updated in the comment box if it still not reconciled.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 18:53:41
User entered '500' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 18:53:35
User opened query 'Per DM CLR-Requery: Response noted. However, dose unit MG is still not recorded in the dose unit section. Please update dose and dose unit as appropriate. Also, kindly refrain from recording as updated in the comment box if it still not reconciled.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:19:43
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		21 Oct 2020 10:19:43
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:11:12
User entered '500mg' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:10:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:52:16
User entered '500'		17 Aug 2020 13:48:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Dawn Killian (b) (4)	26 Oct 2020 18:53:35
	(b) (4)	
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:10:47
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:50
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:49:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:48:47
User entered 'un Feb 2017'	(b) (4), (b) (6)	17 Aug 2020 13:48:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:48:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:48:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:48:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:48:47



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:54:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 13:54:18
Data point term sent to Coder	System	17 Aug 2020 13:52:57
User entered 'Pantoprazole'	(b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '40'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:10:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:52:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:52:45
User entered 'un May 2020'	(b) (4), (b) (6)	17 Aug 2020 13:52:45

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:52:45

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 13:52:45



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:52:45

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:52:45

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 13:57:18
Data point term sent to Coder	System	17 Aug 2020 13:56:02
User entered 'Tadalafil'	(b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'erectile dysfunction'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '20'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:10:59
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:55:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:55:27
User entered 'un Jul 2020'	(b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:55:27

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 13:55:27

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 13:55:27

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 13:55:27

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 01:21:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 01:21:13
Data point term sent to Coder	System	17 Aug 2020 13:57:04
User entered 'tiotropium'	(b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '2.5'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:11:03
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:57:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:56:50
User entered 'un May 2018'	(b) (4), (b) (6)	17 Aug 2020 13:56:50

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50



**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:56:50

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:56:50

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:56:50

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:56:50

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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.	(b) (4) Coder Import (b) (4)	17 Aug 2020 14:01:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 14:01:11
Data point term sent to Coder	System	17 Aug 2020 14:00:09
User entered 'Albuterol'	(b) (4), (b) (6)	17 Aug 2020 14:00:09

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '90'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '4 times a day'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:11:07
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:00:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:00:09
User entered 'un May 2018'	(b) (4), (b) (6)	17 Aug 2020 14:00:09

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 14:00:09

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 14:00:09

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 14:00:09



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 13:59:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 13:59:10
Data point term sent to Coder	System	17 Aug 2020 13:58:08
User entered 'Trazodone'	(b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '100'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49



**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:30:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 14:13:14
User entered 'UN UNK 2019' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:13:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:19:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:11:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 13:57:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 13:57:49
User entered 'un UNK 2016'	(b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 13:57:49

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 13:57:49



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 13:57:49

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 13:57:49

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 00:04:15
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 Aug 2020 00:04:15
Data point term sent to Coder	System	17 Aug 2020 14:03:13
Data point term sent to Coder	System	17 Aug 2020 14:02:13
User entered 'Budesonide/formoterol'	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:30:38
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:14:45
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:14:37
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual medical condition recorded in MH eCRF. Please review and confirm prophylaxis indication if appropriate. Update or provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:24:51
User entered 'Yes (Y)'		17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'COPD'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '160/4.5' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User entered '160/5'	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Aug 2020 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:02:36
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Aug 2020 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:02:36
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Aug 2020 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:02:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:11:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:02:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:02:36
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 14:02:36
User entered 'un May 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Aug 2020 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:02:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:02:07



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Aug 2020 14:02:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:02:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:02:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:02:07
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:02:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 14:02:36
User entered empty.	System	17 Aug 2020 14:02:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 14:02:36
User entered empty.	System	17 Aug 2020 14:02:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:02:36
User entered empty.	System	17 Aug 2020 14:02:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 14:05:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 14:05:17
Data point term sent to Coder	System	17 Aug 2020 14:04:14
User entered 'Bupropion'	(b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '300'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:31:01
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 14:15:50
User entered 'UN UNK 2019' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 14:15:44
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:25:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		17 Aug 2020 18:11:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).		17 Aug 2020 14:03:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:03:47
User entered 'un UNK 2015'	(b) (4), (b) (6)	17 Aug 2020 14:03:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:03:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:03:47

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:03:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CARMELLOSE, PRODUCTSYNONYM: CARBOXYMETHYLCELLULOSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 12:14:26
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 Aug 2020 12:14:26
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	18 Aug 2020 19:21:56 18 Aug 2020 19:21:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CARMELLOSE, PRODUCTSYNONYM: CARBOXYMETHYLCELLULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:08:14
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 Aug 2020 00:08:14
Data point term sent to Coder User entered 'carboxymethylcellulose'	System (b) (4), (b) (6)	17 Aug 2020 14:06:18 17 Aug 2020 14:05:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 19:21:53
User entered 'dry eyes' reason for change: Data Entry Error	System	18 Aug 2020 19:21:53
User opened query 'Data is required. Please complete.' (Site from System).	Dawn Killian (b) (4)	18 Aug 2020 19:21:53
User entered empty.	(b) (4)	
	System	17 Aug 2020 14:05:43
	(b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'l'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '%'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'ophthalmic'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:11:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:05:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:05:43
User entered 'un Dec 2019'	(b) (4), (b) (6)	17 Aug 2020 14:05:43

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 14:05:43

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:05:43

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:05:43



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 14:08:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 14:08:11
Data point term sent to Coder	System	17 Aug 2020 14:07:19
User entered 'enalapril'	(b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:31:16
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 14:16:35
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:30:14
User entered 'Hypertension'		17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '10'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47



**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:11:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:06:47
User entered 'un UNK 2016'	(b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 14:06:47



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:06:47

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:06:47

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 21:55:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:55:36
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4)	24 Sep 2020 14:19:41 24 Sep 2020 14:19:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 14:09:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 14:09:13
Data point term sent to Coder User entered 'Ezetimibe'	System (b) (4), (b) (6)	17 Aug 2020 14:08:22 17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:59:28
Query 'Per MM, Please revise the indication ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:19:23
User entered 'HYPERCHOLESTERLEMIA' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 14:19:16
User opened query 'Per MM, Please revise the indication ' (Site from DM).	(b) (4), (b) (6)	8 Sep 2020 19:55:19
User entered 'Hypertension'		7 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '10'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:11:34
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:07:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:07:44
User entered 'un May 2020'	(b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:07:44

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 14:07:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:07:44

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:07:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 14:10:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 14:10:16
Data point term sent to Coder	System	17 Aug 2020 14:09:25
User entered 'Famotidine'	(b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '20'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:11:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:08:52
User entered 'un May 2020'	(b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:08:52

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 14:08:52

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:08:52

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:08:52

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS GLUCONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 06:41:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:41:18
Data point term sent to Coder	System	17 Aug 2020 14:10:25
User entered 'Ferrous gluconate'	(b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Aug 2020 14:09:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 14:09:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:09:51
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 14:09:40
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:09:40



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Anemia'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '325'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	17 Aug 2020 18:11:42
answered with 'medication is ongoing' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:09:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:09:40
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:09:40

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 14:09:40

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 14:09:40



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
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: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 20:27:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:27:34
Data point term sent to Coder	System	18 Aug 2020 19:23:01
User entered 'cholecalciferol D-3'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Supplement'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '25'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'ug (ug)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'once daily (QD)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Oral (ORAL)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as is' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 13:49:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Dawn Killian (b) (4)	18 Aug 2020 19:23:52
User entered 'UN UNK 2018'	(b) (4)	
	System	18 Aug 2020 19:22:56
	Dawn Killian (b) (4)	18 Aug 2020 19:22:56
	(b) (4)	

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:25:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	18 Aug 2020 19:22:56

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Aug 2020 19:22:56



US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Aug 2020 19:22:56

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 19:22:56

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ERECTILE DYSFUNCTION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:23:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ERECTILE DYSFUNCTION should be recorded, and update con med indication or provide clarification. ' answered with 'As per patient, this was NOT due to worsening. ' (Site from DM).	Antonio Gutierrez (b) (4)	08 Apr 2021 21:06:53
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ERECTILE DYSFUNCTION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:14:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 09:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 09:04:48
Data point term sent to Coder	System	15 Mar 2021 21:51:54
User entered 'testosterone'	Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'erectile dysfunction'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:03:22
User entered 'UNK' reason for change: Data Entry Error	Dawn Killian (b) (4)	12 Apr 2021 20:03:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Mar 2021 21:51:51
	Gerardo Pena (b) (4)	15 Mar 2021 21:51:51
	(b) (4)	

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:03:22
User entered 'Other (OTHER)' reason for change: Data Entry Error	Dawn Killian (b) (4)	12 Apr 2021 20:03:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Mar 2021 21:51:51
	Gerardo Pena (b) (4)	15 Mar 2021 21:51:51
	(b) (4)	

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	12 Apr 2021 20:03:22
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	15 Mar 2021 21:51:51
	(b) (4)	



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:55:13
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' answered with 'end date updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Apr 2021 21:08:49
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:14:48
User entered 'once (ONCE)'	Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'Other (OTHER)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'impant'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:04:41
User entered '20 Feb 2021' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	08 Apr 2021 21:08:29
User entered '28 Feb 2021'	Gerardo Pena (b) (4) (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered '0'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:04:41
User entered 'No (N)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	08 Apr 2021 21:08:29
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:04:41
User entered '20 Feb 2021' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Apr 2021 21:08:29
User entered empty.	Gerardo Pena (b) (4) (b) (4)	15 Mar 2021 21:51:51



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:25:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 21:51:51

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User entered empty.	System	15 Mar 2021 21:51:51

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User entered empty.	System	15 Mar 2021 21:51:51

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:14
User entered empty.	System	15 Mar 2021 21:51:51

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
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: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Apr 2021 23:18:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 23:18:49
Data point term sent to Coder	System	26 Apr 2021 21:15:32
User entered 'Prednisone'	Nathan Cortez (b) (4) (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'Exacerbation of COPD'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '40'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'mg (mg)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'once daily (QD)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'Oral (ORAL)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '29 Mar 2021'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '0'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '01 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:25:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:14:44

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 21:14:44

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 21:14:44

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 21:14:44

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 00:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 00:18:54
Data point term sent to Coder	System	26 Apr 2021 21:17:34
User entered 'Azithromycin'	Nathan Cortez (b) (4) (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'Exacerbation of COPD'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '500'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'mg (mg)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'once daily (QD)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'Oral (ORAL)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered empty.	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07



US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '29 Mar 2021'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '0'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:25:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered '30 Mar 2021'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

US3292158

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:31
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	26 Apr 2021 21:17:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 21:17:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 21:17:07

**US3292158**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:25:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 21:17:07



US3292158

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:25:42**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:08:13
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	04 Feb 2021 16:29:00

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'USA-US072-2021-MRNA-1273-P301000019'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Douglas'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Denham'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '7940 Floyd Curl Drive'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'San Antonio'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '78229'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'US'	(b) (4) System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:59:47
User entered '3'	System	21 Apr 2021 18:49:48
User entered '2'	System	08 Apr 2021 20:14:50
User entered '1'	System	30 Mar 2021 13:30:12



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'USA-US072-2021-MRNA-1273-P301000019'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Douglas'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Denham'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '7940 Floyd Curl Drive'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'San Antonio'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '78229'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'US'	(b) (4) System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:59:47
User entered '3'	System	21 Apr 2021 18:49:48
User entered '2'	System	08 Apr 2021 20:14:50
User entered '1'	System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:25:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '30/Mar/2021 06:30'	(b) (4) System	30 Mar 2021 13:30:12



US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:30:12
User entered '0'		30 Mar 2021 13:30:02

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'USA-US072-2021-MRNA-1273-P301000019'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Douglas'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Denham'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '7940 Floyd Curl Drive'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'San Antonio'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '78229'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'US'	(b) (4) System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:59:47
User entered '3'	System	21 Apr 2021 18:49:48
User entered '2'	System	08 Apr 2021 20:14:50
User entered '1'	System	30 Mar 2021 13:30:12



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:25:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered '08/Apr/2021 16:14'	(b) (4) System	08 Apr 2021 20:14:50

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:25:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 12:59:33
DataPoint Verified.		30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:04:41
User entered 'l'	(b) (4), (b) (6)	08 Apr 2021 20:14:50

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'USA-US072-2021-MRNA-1273-P301000019'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Douglas'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Denham'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '7940 Floyd Curl Drive'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'San Antonio'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '78229'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'US'	(b) (4) System	30 Mar 2021 13:30:12



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:59:47
User entered '3'	System	21 Apr 2021 18:49:48
User entered '2'	System	08 Apr 2021 20:14:50
User entered '1'	System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:25:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:30
User entered '21/Apr/2021 14:49'	(b) (4) System	21 Apr 2021 18:49:48

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:25:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 12:59:33
DataPoint Verified.		30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:30
User entered 'l'	(b) (4), (b) (6)	21 Apr 2021 18:49:48

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'USA-US072-2021-MRNA-1273-P301000019'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Yes (Y)'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'No (N)'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Douglas'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'Denham'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '7940 Floyd Curl Drive'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered 'San Antonio'	System	30 Mar 2021 13:29:38

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:29:57
User entered '78229'	System	30 Mar 2021 13:29:38



**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 21:51:15
Reviewed for Safety.		08 Apr 2021 20:14:27
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 16:25:01
User entered 'US'	(b) (4) System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:25:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 12:59:47
User entered '3'	System	21 Apr 2021 18:49:48
User entered '2'	System	08 Apr 2021 20:14:50
User entered '1'	System	30 Mar 2021 13:30:12

**US3292158**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000019**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:25:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 14:52:20
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:42
User entered '03/May/2021 05:59'	(b) (4) System	03 May 2021 12:59:47

US3292158

Folder: SAE USA-US072-2021-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:25:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 14:52:20
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:42
User entered 'I'	(b) (4), (b) (6)	03 May 2021 12:59:47