

US3712271 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:30:02

All time stamps listed in this document are displayed in GMT

US3712271

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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Participant ID

US3712271

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

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US3712271

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	ALLERGY TO LISINOPRIL
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 (3)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	WISDOM TEETH IMPACTION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	WISDOM TEETH EXTRACTION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	DIABETES MELLITUS TYPE 2
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 (12)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	RESTLESS LEGS SYNDROME
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 (22)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712271

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	OBESITY
Start date (dd MMM yyyy)	20 OCT 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)	OCT 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	ALLERGY TO HYDRALAZINE
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)	_____

US3712271

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	ALLERGY TO MORPHINE
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 (26)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Condition	OBSTRUCTIVE SLEEP APNEA
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)	

US3712271

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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



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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 10:30
Height (xxx.x)	162.4 cm
Weight (xxx.x)	109.6 kg
BMI (xxx.x)	41.55646 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Date of assessment (dd MMM yyyy) 20 OCT 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2013

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3712271

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

<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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	True
<b>Specify</b>	LIVES WITH INDIVIDUALS WHO ARE AT OCCUPATIONAL RISK FOR EXPOSURE.

US3712271

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	VISIT1

US3712271

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

What was the date of randomization? (dd MMM yyyy) 22 OCT 2020

What was the participant's randomization number? 147181

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 ☒

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Height	162.4 cm
Weight	109.9 kg

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Height	162.4 cm
Weight	109.9 kg
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:52
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Height	162.4 cm
Weight	109.9 kg
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:30
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



US3712271

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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) 22 OCT 2020

What was the treatment time? (00:00-23:59) 12:58 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 12:58

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

US3712271

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

12:04 (24 HR)

Collection date and time (derived)

22 OCT 2020 12:04

US3712271

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:06	22 OCT 2020 12:06
Nasopharyngeal Swab 2	No		

US3712271

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**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

98.8 °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

22 OCT 2020 13:33

PC Open Date & Time

22 OCT 2020 13:18

PC Close Date & Time

22 OCT 2020 15:48

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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 97.8 °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	22 OCT 2020 19:53
PC Open Date & Time	22 OCT 2020 16:43
PC Close Date & Time	23 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**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

97.4 °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

23 OCT 2020 19:18

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 23:40

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**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

98.3 °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

25 OCT 2020 23:59

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**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

97.0 °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

26 OCT 2020 21:40

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**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

97.3 °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

27 OCT 2020 13:48

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**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

97.3 °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

28 OCT 2020 13:42

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 13:30

PC Open Date & Time

22 OCT 2020 13:18

PC Close Date & Time

22 OCT 2020 15:48

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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

22 OCT 2020 19:53

PC Open Date & Time

22 OCT 2020 16:43

PC Close Date & Time

23 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**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

23 OCT 2020 19:19

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**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

24 OCT 2020 23:40

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**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

25 OCT 2020 23:59

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**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

26 OCT 2020 21:40

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**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

27 OCT 2020 13:49

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**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

28 OCT 2020 13:42

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**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 ☐

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 13:30
PC Open Date & Time	22 OCT 2020 13:18
PC Close Date & Time	22 OCT 2020 15:48

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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 ☐



US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 19:53
PC Open Date & Time	22 OCT 2020 16:43
PC Close Date & Time	23 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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)

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 19:19
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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)

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 23:40
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 ☒

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 23:59
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 21:40
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 13:49
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 ☒

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 13:43
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3712271

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3712271

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 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

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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)	19 NOV 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 09:55
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:43
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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.*

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

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) 19 NOV 2020

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 19 NOV 2020 11:13

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



US3712271

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 NOV 2020
Collection time (00:00-23:59)	10:02 (24 HR)
Collection date and time (derived)	19 NOV 2020 10:02

US3712271

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Collection date (dd MMM yyyy)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:04	19 NOV 2020 10:04
Nasopharyngeal Swab 2	No		

US3712271

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 11:54

PC Open Date & Time

19 NOV 2020 11:33

PC Close Date & Time

19 NOV 2020 14:03

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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

99.2 °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	19 NOV 2020 21:36
PC Open Date & Time	19 NOV 2020 14:58
PC Close Date & Time	20 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**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

98.3 °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

20 NOV 2020 12:01

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 NOV 2020 02:00

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 00:08

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 05:59

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 12:31

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**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

99.4 °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

25 NOV 2020 12:08

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**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

19 NOV 2020 11:54

PC Open Date & Time

19 NOV 2020 11:33

PC Close Date & Time

19 NOV 2020 14:03

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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

19 NOV 2020 21:36

PC Open Date & Time

19 NOV 2020 14:58

PC Close Date & Time

20 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**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

20 NOV 2020 12:02

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**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

22 NOV 2020 02:00

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**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

23 NOV 2020 00:08

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**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

24 NOV 2020 06:00

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**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

24 NOV 2020 12:31

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**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

25 NOV 2020 12:08

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**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 ☐

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 11:55
PC Open Date & Time	19 NOV 2020 11:33
PC Close Date & Time	19 NOV 2020 14:03

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**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 ☐

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 21:37
PC Open Date & Time	19 NOV 2020 14:58
PC Close Date & Time	20 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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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US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 12:02
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 02:01
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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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US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 06:00
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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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US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 12:32
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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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US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 12:08
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3712271

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:41:05

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3712271

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3712271

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

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) \_\_\_\_\_

US3712271

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

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.*

US3712271

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3712271

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	19 DEC 2020 06:08:06
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 14:53:16
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 75
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	02 JAN 2021 00:02:16
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

<b>TIMEPOINT</b>	DAY 82
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	09 JAN 2021 21:11:56
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 89
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 13:46:16
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 18:00:13
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

31 JAN 2021 01:04:31

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 09:16:55

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

16 FEB 2021 04:52:29

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 10:38:08

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 FEB 2021 03:50:16
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

15 MAR 2021 12:30:18

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

22 MAR 2021 12:29:04

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 11:19:20

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

05 APR 2021 12:00:14

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

13 APR 2021 18:04:53

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☒

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 APR 2021 15:51:47

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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

26 APR 2021 18:41:26

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 08:51:25

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 215

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

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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 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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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 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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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 <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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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 <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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 NOV 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59
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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2022 23:59
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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59



US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**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 ☐

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2022 23:59

US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2022 23:59

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US3712271

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:02

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"/>

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

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[Patient Cloud Open Date & Time](#)

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24 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 DEC 2022 23:59

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US3712271

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:30:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 21:24:05

US3712271

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 23:52:34

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3712271**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

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*



**US3712271**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Date of Contact	14 DEC 2020
Time of Contact	12:04
Date and Time of Contact (derived)	14 DEC 2020 12:04
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

351 of 3939

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	37.5 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.7 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.0 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	101.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	100.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	101.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	80 %	
O2 Saturation Units	%	
Temperature	102.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.0 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 23:31:40

Generated On: 10 Jun 2021 09:30:02

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Date of Visit 14 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Date of Test 14 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☐  
Nasal Swab ☒  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 19 DEC 2020

End Date 21 DEC 2020

Oxygen Saturation 80 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☐

Start Date

End Date

ECMO? Yes ☐ No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☐

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Hepatic Dysfunction? Yes ☐  
No ☐

Start Date

Neurologic Dysfunction? Yes ☐  
No ☐

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3712271

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	18 DEC 2020
Day 7	No	
Day 9	Yes	25 DEC 2020
Day 14	Yes	29 DEC 2020
Day 21	No	
Day 28	No	



US3712271

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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

Visit date (dd MMM yyyy)	14 DEC 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3712271

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	13:45 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 13:45
Height ( <i>xxx.x</i> )	162.4 cm
Weight ( <i>xxx.x</i> )	109.6 kg
Temperature ( <i>xxx.x</i> )	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	92 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3712271

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3712271

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 DEC 2020

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	SICKD28

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 10:56
Height (xxx.x)	162.4 cm
Weight (xxx.x)	109.6 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 JAN 2021



US3712271

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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

Visit date (dd MMM yyyy)	24 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3712271

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Date of updated informed consent ( <i>dd MMM yyyy</i> )	24 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	24 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3712271

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3712271

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	24 FEB 2021
Time of assessment (00:00-23:59)	08:59 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 08:59
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	24 FEB 2021
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:14
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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.*

US3712271

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 09:44

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

US3712271

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

08:43 (24 HR)

Collection date and time (derived)

24 FEB 2021 08:43



US3712271

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00 - 23:59)	08:45
Collection Date and Time (derived)	24 FEB 2021 08:45

US3712271

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712271

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3712271

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

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)	25 MAR 2021
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 09:29
Temperature (xxx.x)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

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)	25 MAR 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 10:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3712271

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

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.*



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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 MAR 2021

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 25 MAR 2021 10:25

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

US3712271

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:14:07

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712271

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 01:14:09

Generated On: 10 Jun 2021 09:30:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:14:09

Generated On: 10 Jun 2021 09:30:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3712271**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3712271

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3712271

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:02

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.*

**US3712271**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>



US3712271

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:29:20

Generated On: 10 Jun 2021 09:30:02

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3712271

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID	USA-US068-2021-MRNA-1273-P30 1000004
Adverse event	BILATERAL PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	21 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

SUBJECT TESTED POSITIVE FOR COVID ON 14DEC2020. SUBJECT BEGAN TO HAVE INCREASED SHORTNESS OF BREATH WITH PULSE OXIMETER SHOWING IN THE 80'S. SUBJECT WENT TO FORT SANDERS REGIONAL MEDICAL CENTER ON 21DEC2020. SUBJECT HAD OXYGEN SATURATION OF 90% WITH AMBULATION. SHE HAD A CHEST X-RAY THAT CONFIRMED COVID PNEUMONIA WITH "GROUND GLASS OPACITIES", GREATEST IN THE LEFT LOBE. SUBJECT ALSO HAD CT PE STUDY THAT WAS NEGATIVE FOR PULMONARY EMBOLISM, BUT AGAIN SHOWED THE COVID PNEUMONIA. TROPONIN RESULTED AT <0.010, UA SHOWED BACTERIURIA, AND SECOND CHEST X RAY SHOWED WORSENING. LAB TESTS SHOW TRANSAMINITIS WITH ALT OF 59 AND AST OF 49, LACTIC ACID OF 3.4, ANION GAP OF 15. EKG SHOWED SINUS TACHYCARDIA WITH A RATE OF 109. COVID-19 TEST WAS POSITIVE. INFLUENZA SWAB WAS NEGATIVE, AND D. DIMER WAS 0.95. SUBJECT WAS DISCHARGED ON 24DEC2020 ON 2L O2 NC.

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

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID	USA-US068-2021-MRNA-1273-P30 1000004
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	11 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID	
Adverse event	TRANSAMINITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID

Adverse event

ASYMPTOMATIC BACTERIURIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID	
Adverse event	ACUTE RESPIRATORY FAILURE WITH HYPOXIA
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)	23 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID	
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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



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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

AEID

Adverse event

LEFT LOWER LOBE PATCHY  
GROUND GLASS OPACITIES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 01 May 2021 22:15:09

Generated On: 10 Jun 2021 09:30:02

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

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

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

Yes ☒

No ☐

---

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

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US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ATENOLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication OZEMPIC

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 0.5

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 (3)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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)		01 SEP 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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 25

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

If dose unit is Other, specify UNITS

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) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (5)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 15

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

If dose unit is Other, specify UNITS

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) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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 (6)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication REQUIP

Prophylaxis Yes ☐

No ☒

Indication RESTLESS LEG SYNDROME

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 (6)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication PROTONIX

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

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 (7)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication EFFEXOR

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 150

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) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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 2004	
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 (9)

Data signed: (b) (4) 23 Apr 2021 21:44:23

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Name of Medication VITAMIN B

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (9)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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 (10)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (10)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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)	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 (12)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ZETIA

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (12)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF COVID-19  
WHILE HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication EZETIMIBE

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ZINC GLUCONATE

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF COVID-19  
WHILE HOSPITALIZED/  
PREVENTION OF COVID

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 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 (16)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 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 (17)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS WHILE  
HOSPITALIZED

Dose per administration 110

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
DEHYDRATION WHILE  
HOSPITALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF PNEUMONIA  
AFTER HOSPITALIZATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

3 TABLETS DAILY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication HOME OXYGEN

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF ACUTE  
RESPIRATORY FAILURE DUE  
TO COVID-19

Dose per administration 2

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

If dose unit is Other, specify LPM

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF PAIN WHILE  
HOSPITALIZED

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication LEVALBUTEROL

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF PNEUMONIA /  
RESPIRATORY FAILURE DUE  
TO COVID-19 WHILE  
HOSPITALIZED

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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 (24)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	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 (26)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication TIZANIDINE

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (27)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
DEHYDRATION DURING  
HOSPITALIZATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF PNEUMONIA  
BACTERIURIA AND SEPSIS  
WHILE HOSPITALIZED

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication IOHEXOL

Prophylaxis Yes ☐  
No ☒

Indication CONTRAST USED FOR IMAGING  
WHILE HOSPITALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
GASTROESOPHAGEAL REFLUX  
DISEASE WHILE HOSPITALIZED

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

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF PNEUMONIA  
DUE TO COVID-19 WHILE  
HOSPITALIZED

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF PNEUMONIA  
DUE TO COVID-19 WHILE  
HOSPITALIZED

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF FEVER WHILE  
HOSPITALIZED

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF DIABETES  
MELLITUS DURING  
HOSPITALIZED

Dose per administration 4

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF DIABETES  
MELLITUS DURING  
HOSPITALIZED

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 WITH MEDS 2 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication REMDESIVIR

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF COVID-19  
WHILE HOSPITALIZED

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF DIABETES  
MELLITUS DURING  
HOSPITALIZED

Dose per administration 30

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☒  
No ☐

Indication TREATMENT OF DIABETES  
MELLITUS DURING  
HOSPITALIZED

Dose per administration 15

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF COVID-19  
WHILE HOSPITALIZED

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Apr 2021 21:44:23

Generated On: 10 Jun 2021 09:30:02

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 00:53:44

Generated On: 10 Jun 2021 09:30:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 DEC 2020	CHEST X-RAY	Adverse Event	
21 DEC 2020	CHEST CT	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:30:02

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: 10 Jun 2021 09:30:02

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 ☐

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/JAN/2021 14:54
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

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/JAN/2021 12:32
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



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/FEB/2021 10:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/FEB/2021 09:33
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

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 08:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 18 Apr 2021 23:31:41

Generated On: 10 Jun 2021 09:30:02

SAEID	USA-US068-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/APR/2021 07:44
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

US3712271 (Prod: Alliance for Multispecialty Research, LLC)

**US3712271**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:30:02**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'US3712271'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 14:08:51

**US3712271**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:17

US3712271

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 14:08:52



**US3712271**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:17

**US3712271**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'SCRN'	System	22 Oct 2020 17:03:17

US3712271

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (Female) and DOB (1975) recorded on this form. However, Year of birth and sex is missing in PPD central lab records. Please confirm if year of birth 1975 and sex female is correct to update in GCL Records.'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 07:34:54
(Site from DM).		
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (Female) and DOB (1975) recorded on this form. However, Year of birth and sex is missing in PPD central lab records. Please confirm if year of birth 1975 and sex female is correct to update in GCL Records.'	(b) (4), (b) (6)	10 Nov 2020 21:17:06
' answered with 'confirmed' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (Female) and DOB (1975) recorded on this form. However, Year of birth and sex is missing in PPD central lab records. Please confirm if year of birth 1975 and sex female is correct to update in GCL Records.'	(b) (4), (b) (6)	10 Nov 2020 03:42:57
(Site from DM).		
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 14:08:53

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '45'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'YEARS'	System	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '45'	System	22 Oct 2020 17:03:42

US3712271

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:02

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
Query 'Per GCL lab recon: Swab: EDC records the sex as Female, however the Sex in PPD central lab for the subject is missing. Please confirm the Sex and update EDC or PPD portal as appropriate.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 06:51:04
' canceled (Site from DM).		
User opened query 'Per GCL lab recon: Swab: EDC records the sex as Female, however the Sex in PPD central lab for the subject is missing. Please confirm the Sex and update EDC or PPD portal as appropriate.	(b) (4), (b) (6)	30 Nov 2020 14:03:40
' (Site from DM).		
User entered 'Female (F)'	(b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31



**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31



**US3712271**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:30:02**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:31

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Oct 2020'	System	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42



**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:03:42

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Oct 2020 14:08:52

**US3712271**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:30:02**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'I'	System	22 Oct 2020 17:04:09

**US3712271**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:09

**US3712271**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:30:02**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:44:44

US3712271

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
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.	Coder Import (b) (4)	26 Oct 2020 12:55:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 12:55:28
Data point term sent to Coder	System	26 Oct 2020 11:45:46
User entered 'allergy to statins'	(b) (4), (b) (6)	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:19



**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2008'	System	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2008'	System	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:19

**US3712271**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:19

US3712271

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
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.	Coder Import (b) (4)	26 Oct 2020 11:46:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:46:36
Data point term sent to Coder	System	26 Oct 2020 11:45:46
User entered 'allergy to lisinopril'	(b) (4), (b) (6)	26 Oct 2020 11:45:43



**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2015'	System	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2015'	System	26 Oct 2020 11:45:43

**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:43



**US3712271**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:43

US3712271

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:24
Data point term sent to Coder	System	26 Oct 2020 11:46:48
User entered 'myopia'	(b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1985'	System	26 Oct 2020 11:45:52



**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1985'	System	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:52

**US3712271**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:45:52

US3712271

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:47:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:47:39
Data point term sent to Coder	System	26 Oct 2020 11:46:48
User entered 'wisdom teeth impaction'	(b) (4), (b) (6)	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:08



**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1999'	System	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1999'	System	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1999'	System	26 Oct 2020 11:46:08

**US3712271**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1999'	System	26 Oct 2020 11:46:08

US3712271

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:47:40
Data point term sent to Coder	System	26 Oct 2020 11:46:48
User entered 'wisdom teeth extraction'	(b) (4), (b) (6)	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:22



**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1999'	System	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1999'	System	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1999'	System	26 Oct 2020 11:46:22

**US3712271**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1999'	System	26 Oct 2020 11:46:22

US3712271

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
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.	Coder Import (b) (4)	26 Oct 2020 11:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:47:40
Data point term sent to Coder	System	26 Oct 2020 11:46:46
User entered 'tonsillitis'	(b) (4), (b) (6)	26 Oct 2020 11:46:38



**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2005'	System	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2005'	System	26 Oct 2020 11:46:38

**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2005'	System	26 Oct 2020 11:46:38



**US3712271**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2005'	System	26 Oct 2020 11:46:38

US3712271

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
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.	Coder Import (b) (4)	26 Oct 2020 11:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:40
Data point term sent to Coder	System	26 Oct 2020 11:47:49
User entered 'tonsillectomy'	(b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2005'	System	26 Oct 2020 11:46:51



**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2005'	System	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2005'	System	26 Oct 2020 11:46:51

**US3712271**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2005'	System	26 Oct 2020 11:46:51

US3712271

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Adenoiditis, LLT: Adenoiditis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:39
Data point term sent to Coder	System	26 Oct 2020 11:47:49
User entered 'adenoiditis'	(b) (4), (b) (6)	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:06



**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1998'	System	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1998'	System	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1998'	System	26 Oct 2020 11:47:06

**US3712271**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1998'	System	26 Oct 2020 11:47:06

US3712271

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenoidectomy, LLT: Adenoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:40
Data point term sent to Coder	System	26 Oct 2020 11:47:49
User entered 'adenoidectomy'	(b) (4), (b) (6)	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:19



**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1998'	System	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1998'	System	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1998'	System	26 Oct 2020 11:47:19

**US3712271**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1998'	System	26 Oct 2020 11:47:19

US3712271

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:48:40
Data point term sent to Coder	System	26 Oct 2020 11:47:51
User entered 'hypertension'	(b) (4), (b) (6)	26 Oct 2020 11:47:30



**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2000'	System	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2000'	System	26 Oct 2020 11:47:30

**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:47:30



**US3712271**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:47:30

US3712271

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
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.	Coder Import (b) (4)	26 Oct 2020 11:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:49:43
Data point term sent to Coder	System	26 Oct 2020 11:48:51
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2012'	System	26 Oct 2020 11:48:01



**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2012'	System	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:01

**US3712271**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:01

US3712271

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:49:43
Data point term sent to Coder	System	26 Oct 2020 11:48:51
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:33



**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2008'	System	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2008'	System	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:33

**US3712271**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:33

US3712271

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:49:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:49:42
Data point term sent to Coder	System	26 Oct 2020 11:48:51
User entered 'acid reflux'	(b) (4), (b) (6)	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:43



**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2010'	System	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2010'	System	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:43

**US3712271**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:48:43

US3712271

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
Data point term sent to Coder	System	26 Oct 2020 11:49:54
User entered 'appendicitis'	(b) (4), (b) (6)	26 Oct 2020 11:48:59



**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:48:59

**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:48:59



**US3712271**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:48:59

US3712271

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
Data point term sent to Coder	System	26 Oct 2020 11:49:52
User entered 'appendectomy'	(b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:49:18



**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:49:18

**US3712271**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:49:18

US3712271

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:37
Data point term sent to Coder	System	26 Oct 2020 11:49:54
User entered 'cholecystitis'	(b) (4), (b) (6)	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:36



**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2016'	System	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2016'	System	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2016'	System	26 Oct 2020 11:49:36

**US3712271**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2016'	System	26 Oct 2020 11:49:36

US3712271

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:50:38
Data point term sent to Coder	System	26 Oct 2020 11:49:54
User entered 'cholecystectomy'	(b) (4), (b) (6)	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:52



**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2016'	System	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2016'	System	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2016'	System	26 Oct 2020 11:49:52

**US3712271**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2016'	System	26 Oct 2020 11:49:52

US3712271

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Bleeding menstrual heavy - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 11:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 11:51:40
Data point term sent to Coder	System	26 Oct 2020 11:50:55
User entered 'heavy menses'	(b) (4), (b) (6)	26 Oct 2020 11:50:17



**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:50:17

**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:50:17



**US3712271**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:50:17

US3712271

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:51:40
Data point term sent to Coder	System	26 Oct 2020 11:50:57
User entered 'hysterectomy'	(b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:50:28



**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Oct 2020 11:50:28

**US3712271**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Oct 2020 11:50:28

US3712271

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 12:57:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 12:57:34
Data point term sent to Coder	System	26 Oct 2020 11:51:58
User entered 'mild osteoarthritis (hands)'	(b) (4), (b) (6)	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:07



**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Feb 2020'	System	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:07

**US3712271**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:07

US3712271

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless legs syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:52:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:52:42
Data point term sent to Coder	System	26 Oct 2020 11:51:58
User entered 'Restless legs syndrome'	(b) (4), (b) (6)	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:17



**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2017'	System	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2017'	System	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:17

**US3712271**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:17

US3712271

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:52:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 11:52:43
Data point term sent to Coder	System	26 Oct 2020 11:51:57
User entered 'anxiety'	(b) (4), (b) (6)	26 Oct 2020 11:51:28



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**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2004'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2004'	System	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2004'	System	26 Oct 2020 11:51:28

**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:28



**US3712271**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Oct 2020 11:51:28

US3712271

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:44:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:44:05
Data point term sent to Coder	System	22 Jan 2021 20:43:37
User entered 'obesity'	(b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Oct 2020'	System	22 Jan 2021 20:42:43



**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	22 Jan 2021 20:42:43

**US3712271**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	22 Jan 2021 20:42:43

US3712271

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
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.	Coder Import (b) (4)	04 Mar 2021 21:20:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:20:43
Data point term sent to Coder	System	26 Feb 2021 15:05:32
User entered 'allergy to hydralazine'	(b) (4), (b) (6)	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:04:51



**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2015'	System	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2015'	System	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:04:51

**US3712271**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:04:51

US3712271

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
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: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:20:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:20:50
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: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:05:51
Data point term sent to Coder	System	26 Feb 2021 15:05:31
User entered 'allergy to morphine'	(b) (4), (b) (6)	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:07



**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2005'	System	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2005'	System	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:05:07

**US3712271**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:05:07

US3712271

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
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.	Coder Import (b) (4)	26 Feb 2021 15:07:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:07:51
Data point term sent to Coder	System	26 Feb 2021 15:06:33
User entered 'allergy to avelox'	(b) (4), (b) (6)	26 Feb 2021 15:05:37



**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1995'	System	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1995'	System	26 Feb 2021 15:05:37

**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:05:37



**US3712271**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:05:37

US3712271

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:50
Data point term sent to Coder	System	26 Feb 2021 15:06:34
User entered 'allergy to levaquin'	(b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1995'	System	26 Feb 2021 15:06:06



**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1995'	System	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:06

**US3712271**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:06

US3712271

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:07:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:07:52
Data point term sent to Coder	System	26 Feb 2021 15:06:34
User entered 'obstructive sleep apnea'	(b) (4), (b) (6)	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:20



**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2013'	System	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2013'	System	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:20

**US3712271**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:20

US3712271

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per MM, please review and update the type of tachycardia' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:20:07
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:40:59
Query 'Per MM, please review and update the type of tachycardia' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:40:35
Data point term sent to Coder	System	14 Apr 2021 12:39:40
Coding entries removed.	(b) (4), (b) (6)	14 Apr 2021 12:39:08
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 12:39:08
User entered 'sinus TACHYCARDIA' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 12:39:08
User opened query 'Per MM, please review and update the type of tachycardia' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 01:07:15
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 15:08:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 15:08:53
Data point term sent to Coder	System	26 Feb 2021 15:07:35
User entered 'tachycardia'	(b) (4), (b) (6)	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:39



**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2000'	System	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2000'	System	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:39

**US3712271**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:06:39

US3712271

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:36:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:36:47
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:38:57
Data point term sent to Coder	System	26 Feb 2021 15:09:38
User entered 'allergy to hydralazine angioedema'	(b) (4), (b) (6)	26 Feb 2021 15:08:41



**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1995'	System	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1995'	System	26 Feb 2021 15:08:41

**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:08:41



**US3712271**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:08:41

US3712271

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Chronic diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:25:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:25:50
Data point term sent to Coder	System	26 Feb 2021 15:09:44
User entered 'chronic diarrhea'	(b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 1995'	System	26 Feb 2021 15:09:00



**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '1995'	System	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:09:00

**US3712271**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:09:00

US3712271

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Trigger finger, LLT: Trigger finger - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:52
Data point term sent to Coder	System	26 Feb 2021 15:21:56
User entered 'trigger finger'	(b) (4), (b) (6)	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '01 Jan 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:33



**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2020'	System	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Sep 2020'	System	26 Feb 2021 15:21:33

**US3712271**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	26 Feb 2021 15:21:33

US3712271

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon sheath incision, LLT: Trigger finger release - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:22:54
Data point term sent to Coder	System	26 Feb 2021 15:21:56
User entered 'trigger finger repair'	(b) (4), (b) (6)	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:50



**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Sep 2020'	System	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Sep 2020'	System	26 Feb 2021 15:21:50

**US3712271**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2020'	System	26 Feb 2021 15:21:50

US3712271

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:30:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:23:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:23:52
Data point term sent to Coder	System	26 Feb 2021 15:22:56
User entered 'fatigue'	(b) (4), (b) (6)	26 Feb 2021 15:22:03



**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:38:57
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2010'	System	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2010'	System	26 Feb 2021 15:22:03

**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:22:03



**US3712271**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	26 Feb 2021 15:22:03

US3712271

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:30:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 20:16:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 20:16:51
Data point term sent to Coder	System	22 Mar 2021 20:00:33
User entered 'insomnia'	(b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'Jan 2018'	System	22 Mar 2021 19:59:46



**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '2018'	System	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	22 Mar 2021 19:59:46

**US3712271**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered empty.	System	22 Mar 2021 19:59:46

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '10:30' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '20 Oct 2020 10:30'	System	26 Oct 2020 11:43:28
User entered empty.	System	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '162.4' cm	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:15
DataPoint set to visible.	System	22 Oct 2020 17:04:09



US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '109.6' kg	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:15
DataPoint set to visible.	System	22 Oct 2020 17:04:09

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered '41.55646'	System	26 Oct 2020 11:41:15
DataPoint set to visible.	System	22 Oct 2020 17:04:09

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'kg/m2'	System	26 Oct 2020 11:41:15
DataPoint set to visible.	System	22 Oct 2020 17:04:09

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '37.1' C reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:43:28
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'bpm'	System	26 Oct 2020 11:43:28
User entered empty.	System	26 Oct 2020 11:41:15



US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'breaths/min'	System	26 Oct 2020 11:43:28
User entered empty.	System	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '145' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'mmHg'	System	26 Oct 2020 11:43:28
User entered empty.	System	26 Oct 2020 11:41:15

US3712271

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	26 Oct 2020 11:43:28
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 11:43:28
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 11:43:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 11:41:15
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User entered 'mmHg'	System	26 Oct 2020 11:43:28
User entered empty.	System	26 Oct 2020 11:41:15

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25

**US3712271**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25



**US3712271**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:43:40

**US3712271**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:43:40

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50



**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

**US3712271**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:30:02**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:41:50

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56



US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

**US3712271**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:30:02**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

**US3712271**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:30:02**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56



US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

**US3712271**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:30:02**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

US3712271

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:52:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Lives with individuals who are at occupational risk for exposure.'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:42:56

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:27



**US3712271**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:27

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:27

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'VISIT1'	System	22 Oct 2020 17:04:27

US3712271

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:44

US3712271

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:02

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '147181'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:44

US3712271

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 16:28:44

US3712271

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:02

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)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:19

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:30:02**

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)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:19



US3712271

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:02

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User closed query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 10:43:21
Query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' answered with 'added' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:42:47
User opened query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:40:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 17:10:19

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:30:02**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:19

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:30:02**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:19

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:30:02**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:19
DataPoint set to visible.	System	22 Oct 2020 17:03:42

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '162.4' cm	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '109.9' kg	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '162.4' cm	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '109.9' kg	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50



US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '11:52'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '22 Oct 2020 11:52'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50



**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '85'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'bpm'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '17'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'breaths/min'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '136'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'mmHg'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '84'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'mmHg'	System	26 Oct 2020 12:12:50



US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '162.4' cm	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '109.9' kg	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '13:30'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '22 Oct 2020 13:30'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50



US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '87'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'bpm'	System	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'breaths/min'	System	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '134'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'mmHg'	System	26 Oct 2020 12:12:50



US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '89'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 12:12:50

US3712271

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'mmHg'	System	26 Oct 2020 12:12:50

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:36

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

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)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 17:11:05



US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '12:58'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '22 Oct 2020 12:58'	System	22 Oct 2020 17:11:05

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:11:05

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'ONCE'	System	22 Oct 2020 17:11:05

US3712271

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:27

US3712271

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:27



**US3712271**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '12:04'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:27

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '22 Oct 2020 12:04'	System	22 Oct 2020 17:10:27

US3712271

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '12:06'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '22 Oct 2020 12:06'	System	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Oct 2020 17:10:36



US3712271

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:20:10
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:36

US3712271

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:20:10
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '12:06'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:36

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered empty.	System	12 Mar 2021 21:20:10
User entered '22 Oct 2020 12:06'	System	22 Oct 2020 17:10:36

US3712271

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:30:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:40

**US3712271**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered '1'	System	22 Oct 2020 17:10:40

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:31:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '662fa7b6-349e-4dda-b404-839d8333a1c0' User entered 'Yes (Y)'	System	22 Oct 2020 17:33:28
	System	22 Oct 2020 17:33:28

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:33:20', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '662fa7b6-349e-4dda-b404-839d8333a1c0' User entered '98.8'	System	22 Oct 2020 17:33:28
	System	22 Oct 2020 17:33:28



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:33:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '662fa7b6-349e-4dda-b404-839d8333a1c0'	System	22 Oct 2020 17:33:28
User entered 'No (N)'	System	22 Oct 2020 17:33:28

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:33:25', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '662fa7b6-349e-4dda-b404-839d8333a1c0' User entered '22 Oct 2020 13:33'	System	22 Oct 2020 17:33:28
	System	22 Oct 2020 17:33:28

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 13:18'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 15:48'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e4739321-2de5-430c-ae23-dabc2f42571f' User entered 'Yes (Y)'	System	22 Oct 2020 23:53:44
	System	22 Oct 2020 23:53:44

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e4739321-2de5-430c-ae23-dabc2f42571f' User entered '97.8'	System	22 Oct 2020 23:53:44
	System	22 Oct 2020 23:53:44

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:38', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e4739321-2de5-430c-ae23-dabc2f42571f' User entered 'No (N)'	System	22 Oct 2020 23:53:44
	System	22 Oct 2020 23:53:44



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:41', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e4739321-2de5-430c-ae23-dabc2f42571f' User entered '22 Oct 2020 19:53'	System	22 Oct 2020 23:53:44
	System	22 Oct 2020 23:53:44

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 16:43'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 2'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '210d7728-caeb-42a3-a0f6-fd430881b72f' User entered 'Yes (Y)'	System	23 Oct 2020 23:18:54
	System	23 Oct 2020 23:18:54

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '210d7728-caeb-42a3-a0f6-fd430881b72f' User entered '97.4'	System	23 Oct 2020 23:18:54
	System	23 Oct 2020 23:18:54

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '210d7728-caeb-42a3-a0f6-fd430881b72f' User entered 'No (N)'	System	23 Oct 2020 23:18:54
	System	23 Oct 2020 23:18:54

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '210d7728-caeb-42a3-a0f6-fd430881b72f' User entered '23 Oct 2020 19:18'	System	23 Oct 2020 23:18:54
	System	23 Oct 2020 23:18:54



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 3'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:22', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fd360ae4-50d2-4b7a-af3e-01818096fbd8' User entered 'Yes (Y)'	System	25 Oct 2020 03:40:35
	System	25 Oct 2020 03:40:35

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fd360ae4-50d2-4b7a-af3e-01818096fbd8' User entered '98.0'	System	25 Oct 2020 03:40:35
	System	25 Oct 2020 03:40:35

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:30', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fd360ae4-50d2-4b7a-af3e-01818096fbd8'	System	25 Oct 2020 03:40:35
User entered 'No (N)'	System	25 Oct 2020 03:40:35

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:33', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fd360ae4-50d2-4b7a-af3e-01818096fbd8' User entered '24 Oct 2020 23:40'	System	25 Oct 2020 03:40:35
	System	25 Oct 2020 03:40:35

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:11:05



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 4'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:11', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a88136f1-c9be-45d9-a71d-43eab6535164' User entered 'Yes (Y)'	System	26 Oct 2020 03:59:23
	System	26 Oct 2020 03:59:23

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:15', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a88136f1-c9be-45d9-a71d-43eab6535164' User entered '98.3'	System	26 Oct 2020 03:59:23
	System	26 Oct 2020 03:59:23

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:17', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a88136f1-c9be-45d9-a71d-43eab6535164' User entered 'No (N)'	System	26 Oct 2020 03:59:23
	System	26 Oct 2020 03:59:23

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:20', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a88136f1-c9be-45d9-a71d-43eab6535164' User entered '25 Oct 2020 23:59'	System	26 Oct 2020 03:59:23
	System	26 Oct 2020 03:59:23

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:11:05



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 5'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:39:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0cd5370f-976f-415a-a3a6-cb87f75289d6'	System	27 Oct 2020 01:40:37
User entered 'Yes (Y)'	System	27 Oct 2020 01:40:37

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0cd5370f-976f-415a-a3a6-cb87f75289d6' User entered '97.0'	System	27 Oct 2020 01:40:37
	System	27 Oct 2020 01:40:37

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0cd5370f-976f-415a-a3a6-cb87f75289d6'	System	27 Oct 2020 01:40:37
User entered 'No (N)'	System	27 Oct 2020 01:40:37

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:33', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0cd5370f-976f-415a-a3a6-cb87f75289d6' User entered '26 Oct 2020 21:40'	System	27 Oct 2020 01:40:37
	System	27 Oct 2020 01:40:37

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 6'	System	22 Oct 2020 17:11:05



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:18', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bbb5ff62-68e2-4bc0-8738-72b6b20daf60' User entered 'Yes (Y)'	System	27 Oct 2020 17:48:30
	System	27 Oct 2020 17:48:30

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bbb5ff62-68e2-4bc0-8738-72b6b20daf60' User entered '97.3'	System	27 Oct 2020 17:48:30
	System	27 Oct 2020 17:48:30

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:24', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bbb5ff62-68e2-4bc0-8738-72b6b20daf60' User entered 'No (N)'	System	27 Oct 2020 17:48:30
	System	27 Oct 2020 17:48:30

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bbb5ff62-68e2-4bc0-8738-72b6b20daf60' User entered '27 Oct 2020 13:48'	System	27 Oct 2020 17:48:30
	System	27 Oct 2020 17:48:30

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 7'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ed7a1f88-d0b0-4216-8af4-4b546f1d92f4' User entered 'Yes (Y)'	System	28 Oct 2020 17:42:53
	System	28 Oct 2020 17:42:53



US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:39', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ed7a1f88-d0b0-4216-8af4-4b546f1d92f4' User entered '97.3'	System	28 Oct 2020 17:42:53
	System	28 Oct 2020 17:42:53

US3712271

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ed7a1f88-d0b0-4216-8af4-4b546f1d92f4'	System	28 Oct 2020 17:42:53
User entered 'No (N)'	System	28 Oct 2020 17:42:53

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ed7a1f88-d0b0-4216-8af4-4b546f1d92f4' User entered '28 Oct 2020 13:42'	System	28 Oct 2020 17:42:53
	System	28 Oct 2020 17:42:53

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:29:51', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '28fbcf22-2a79-4b16-b677-b1de5d619326' User entered 'None (1)'	System	22 Oct 2020 17:30:16
	System	22 Oct 2020 17:30:16

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '28fbcf22-2a79-4b16-b677-b1de5d619326' User entered 'No (N)'	System	22 Oct 2020 17:30:16
	System	22 Oct 2020 17:30:16



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '28fbcf22-2a79-4b16-b677-b1de5d619326' User entered 'No (N)'	System	22 Oct 2020 17:30:16
	System	22 Oct 2020 17:30:16

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '28fbcf22-2a79-4b16-b677-b1de5d619326' User entered 'None (1)'	System	22 Oct 2020 17:30:16
	System	22 Oct 2020 17:30:16

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:11', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '28fbcf22-2a79-4b16-b677-b1de5d619326' User entered '22 Oct 2020 13:30'	System	22 Oct 2020 17:30:16
	System	22 Oct 2020 17:30:16

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 13:18'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 15:48'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:18', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '2347c341-6f60-43e0-a88a-69111294d599'	System	22 Oct 2020 23:53:28
User entered 'None (1)'	System	22 Oct 2020 23:53:28

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:20', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '2347c341-6f60-43e0-a88a-69111294d599'	System	22 Oct 2020 23:53:28
User entered 'No (N)'	System	22 Oct 2020 23:53:28



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:22', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '2347c341-6f60-43e0-a88a-69111294d599' User entered 'No (N)'	System	22 Oct 2020 23:53:28
	System	22 Oct 2020 23:53:28

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '2347c341-6f60-43e0-a88a-69111294d599'	System	22 Oct 2020 23:53:28
User entered 'None (1)'	System	22 Oct 2020 23:53:28

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:25', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '2347c341-6f60-43e0-a88a-69111294d599'	System	22 Oct 2020 23:53:28
User entered '22 Oct 2020 19:53'	System	22 Oct 2020 23:53:28

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 16:43'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 2'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bad5fe64-c0b3-4caa-934c-1f24a6176235'	System	23 Oct 2020 23:19:11
User entered 'None (1)'	System	23 Oct 2020 23:19:11

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:18:59', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bad5fe64-c0b3-4caa-934c-1f24a6176235' User entered 'No (N)'	System	23 Oct 2020 23:19:11
	System	23 Oct 2020 23:19:11



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bad5fe64-c0b3-4caa-934c-1f24a6176235'	System	23 Oct 2020 23:19:11
User entered 'No (N)'	System	23 Oct 2020 23:19:11

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bad5fe64-c0b3-4caa-934c-1f24a6176235'	System	23 Oct 2020 23:19:11
User entered 'None (1)'	System	23 Oct 2020 23:19:11

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:08', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bad5fe64-c0b3-4caa-934c-1f24a6176235'	System	23 Oct 2020 23:19:11
User entered '23 Oct 2020 19:19'	System	23 Oct 2020 23:19:11

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 3'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:10', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c2c08cd-8b1d-4caa-ad18-8bd4ca8c40d0' User entered 'None (1)'	System	25 Oct 2020 03:40:21
	System	25 Oct 2020 03:40:21

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:12', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c2c08cd-8b1d-4caa-ad18-8bd4ca8c40d0' User entered 'No (N)'	System	25 Oct 2020 03:40:21
	System	25 Oct 2020 03:40:21



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:14', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c2c08cd-8b1d-4caa-ad18-8bd4ca8c40d0' User entered 'No (N)'	System	25 Oct 2020 03:40:21
	System	25 Oct 2020 03:40:21

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:15', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c2c08cd-8b1d-4caa-ad18-8bd4ca8c40d0' User entered 'None (1)'	System	25 Oct 2020 03:40:21
	System	25 Oct 2020 03:40:21

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:18', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c2c08cd-8b1d-4caa-ad18-8bd4ca8c40d0' User entered '24 Oct 2020 23:40'	System	25 Oct 2020 03:40:21
	System	25 Oct 2020 03:40:21

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 4'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:39', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fa59d5a3-68d9-4f44-ba37-61a6a4f4fa6e' User entered 'None (1)'	System	26 Oct 2020 03:59:51
	System	26 Oct 2020 03:59:51

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:41', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fa59d5a3-68d9-4f44-ba37-61a6a4f4fa6e' User entered 'No (N)'	System	26 Oct 2020 03:59:51
	System	26 Oct 2020 03:59:51



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:43', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fa59d5a3-68d9-4f44-ba37-61a6a4f4fa6e' User entered 'No (N)'	System	26 Oct 2020 03:59:51
	System	26 Oct 2020 03:59:51

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fa59d5a3-68d9-4f44-ba37-61a6a4f4fa6e'	System	26 Oct 2020 03:59:51
User entered 'None (1)'	System	26 Oct 2020 03:59:51

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fa59d5a3-68d9-4f44-ba37-61a6a4f4fa6e' User entered '25 Oct 2020 23:59'	System	26 Oct 2020 03:59:51
	System	26 Oct 2020 03:59:51

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 5'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bb15e157-4e05-4461-bdb9-a9c12ef8b0f9'	System	27 Oct 2020 01:40:44
User entered 'None (1)'	System	27 Oct 2020 01:40:44

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bb15e157-4e05-4461-bdb9-a9c12ef8b0f9' User entered 'No (N)'	System	27 Oct 2020 01:40:44
	System	27 Oct 2020 01:40:44



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:38', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bb15e157-4e05-4461-bdb9-a9c12ef8b0f9' User entered 'No (N)'	System	27 Oct 2020 01:40:44
	System	27 Oct 2020 01:40:44

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bb15e157-4e05-4461-bdb9-a9c12ef8b0f9'	System	27 Oct 2020 01:40:44
User entered 'None (1)'	System	27 Oct 2020 01:40:44

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'bb15e157-4e05-4461-bdb9-a9c12ef8b0f9' User entered '26 Oct 2020 21:40'	System	27 Oct 2020 01:40:44
	System	27 Oct 2020 01:40:44

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 6'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:38', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '526a66bd-2fcc-494a-b6d5-8b2df84dcf8f' User entered 'None (1)'	System	27 Oct 2020 17:49:54
	System	27 Oct 2020 17:49:54

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:41', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '526a66bd-2fcc-494a-b6d5-8b2df84dcf8f' User entered 'No (N)'	System	27 Oct 2020 17:49:54
	System	27 Oct 2020 17:49:54



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:43', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '526a66bd-2fcc-494a-b6d5-8b2df84dcf8f' User entered 'No (N)'	System	27 Oct 2020 17:49:54
	System	27 Oct 2020 17:49:54

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '526a66bd-2fcc-494a-b6d5-8b2df84dcf8f' User entered 'None (1)'	System	27 Oct 2020 17:49:54
	System	27 Oct 2020 17:49:54

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '526a66bd-2fcc-494a-b6d5-8b2df84dcf8f' User entered '27 Oct 2020 13:49'	System	27 Oct 2020 17:49:54
	System	27 Oct 2020 17:49:54

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 7'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:51', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0bf5bab9-9076-4765-ac71-acb104cf195e' User entered 'None (1)'	System	28 Oct 2020 17:43:03
	System	28 Oct 2020 17:43:03

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0bf5bab9-9076-4765-ac71-acb104cf195e' User entered 'No (N)'	System	28 Oct 2020 17:43:03
	System	28 Oct 2020 17:43:03



US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:55', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0bf5bab9-9076-4765-ac71-acb104cf195e' User entered 'No (N)'	System	28 Oct 2020 17:43:03
	System	28 Oct 2020 17:43:03

US3712271

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:56', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0bf5bab9-9076-4765-ac71-acb104cf195e' User entered 'None (1)'	System	28 Oct 2020 17:43:03
	System	28 Oct 2020 17:43:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:42:59', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0bf5bab9-9076-4765-ac71-acb104cf195e' User entered '28 Oct 2020 13:42'	System	28 Oct 2020 17:43:03
	System	28 Oct 2020 17:43:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:26', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:28', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:29', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:32', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'None (0)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered 'No (N)'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T13:30:38', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c6b2d170-a941-4bcf-91bc-67104b8bc78d' User entered '22 Oct 2020 13:30'	System	22 Oct 2020 17:30:40
	System	22 Oct 2020 17:30:40

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 13:18'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 15:48'	System	22 Oct 2020 17:11:05



US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:09', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:10', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'None (0)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:13', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered 'No (N)'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-22T19:53:15', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0b22325b-3374-471b-b1cb-bcc1d9669779' User entered '22 Oct 2020 19:53'	System	22 Oct 2020 23:53:17
	System	22 Oct 2020 23:53:17

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Oct 2020 16:43'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 2'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:12', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:14', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:17', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:19', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'None (0)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:26', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered 'No (N)'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-23T19:19:29', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3d07843f-b9b6-4f07-bbc6-53801aa74df0' User entered '23 Oct 2020 19:19'	System	23 Oct 2020 23:19:32
	System	23 Oct 2020 23:19:32

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 3'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:39:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:39:58', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:39:59', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'None (0)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered 'No (N)'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-24T23:40:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '346b3a75-7de4-4fef-8394-c26440208c0b' User entered '24 Oct 2020 23:40'	System	25 Oct 2020 03:40:09
	System	25 Oct 2020 03:40:09

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:11:05



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 4'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:25', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:28', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:29', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:32', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'None (0)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40



US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered 'No (N)'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-25T23:59:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ce9ad88e-f3d6-418d-8966-a0c91a9173b3' User entered '25 Oct 2020 23:59'	System	26 Oct 2020 03:59:40
	System	26 Oct 2020 03:59:40

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 5'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:46', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03



US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:51', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'None (0)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:55', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered 'No (N)'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-26T21:40:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8969d1b0-49a1-4732-b484-61e58b0b0c7a' User entered '26 Oct 2020 21:40'	System	27 Oct 2020 01:41:03
	System	27 Oct 2020 01:41:03

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 6'	System	22 Oct 2020 17:11:05



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8'	System	27 Oct 2020 17:49:41
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:49:41

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8'	System	27 Oct 2020 17:49:41
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:49:41

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:48:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8'	System	27 Oct 2020 17:49:41
User entered 'No interference with activity (1)'	System	27 Oct 2020 17:49:41

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8'	System	27 Oct 2020 17:49:41
User entered 'Some interference with activity (2)'	System	27 Oct 2020 17:49:41

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8' User entered 'None (0)'	System	27 Oct 2020 17:49:41
	System	27 Oct 2020 17:49:41

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8' User entered 'None (0)'	System	27 Oct 2020 17:49:41
	System	27 Oct 2020 17:49:41

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:19', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8' User entered 'No (N)'	System	27 Oct 2020 17:49:41
	System	27 Oct 2020 17:49:41

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-27T13:49:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '6cf06d81-078d-4536-b24f-bb6c62d971e8' User entered '27 Oct 2020 13:49'	System	27 Oct 2020 17:49:41
	System	27 Oct 2020 17:49:41



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	22 Oct 2020 17:11:05
User entered 'Day 7'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:14', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:17', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27



**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:19', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'None (0)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

US3712271

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered 'No (N)'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-10-28T13:43:24', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '1f3a78cc-b607-4bdd-b25a-bc0e46e6684f' User entered '28 Oct 2020 13:43'	System	28 Oct 2020 17:43:27
	System	28 Oct 2020 17:43:27

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:11:05

**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:14:35

**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:14:35

**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:14:35



**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:14:35

**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 18:14:37

**US3712271**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'I'	System	02 Nov 2020 18:14:37

**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:13

**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:13

**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:13

**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:13

**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:01:16



**US3712271**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:18
User entered 'I'	System	10 Nov 2020 15:01:16

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:56

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:56

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:56

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:56

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:19:50

**US3712271**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:46:25
User entered 'I'	System	19 Nov 2020 16:19:50

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:19:58



**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:19:58

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:19:58

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'VISIT2'	System	19 Nov 2020 16:19:58

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '09:55'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '19 Nov 2020 09:55'	System	24 Nov 2020 14:07:15



US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '99'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'bpm'	System	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'breaths/min'	System	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '128'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15



US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'mmHg'	System	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '78'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'mmHg'	System	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '11:43'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '19 Nov 2020 11:43'	System	24 Nov 2020 14:07:15



US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '37.3' C	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '90'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'bpm'	System	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'breaths/min'	System	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '128'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15



**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'mmHg'	System	24 Nov 2020 14:07:15

US3712271

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '84'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'mmHg'	System	24 Nov 2020 14:07:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:15

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

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)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11



**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '11:13'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '19 Nov 2020 11:13'	System	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'ONCE'	System	19 Nov 2020 16:22:11

US3712271

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:26



US3712271

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:26

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '10:02'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:26

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '19 Nov 2020 10:02'	System	19 Nov 2020 16:20:26

US3712271

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '10:04'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '19 Nov 2020 10:04'	System	19 Nov 2020 16:20:38



**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:20:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:20:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:20:18
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '10:04'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:20:38

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	12 Mar 2021 21:20:18
User entered '19 Nov 2020 10:04'	System	19 Nov 2020 16:20:38

US3712271

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User closed query 'Per GCL Lab Recon: Sample was reported under Visit OI-1 dated 24Feb2021 in PPD Central lab; however Visit OI-1 is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:27:07
Query 'Per GCL Lab Recon: Sample was reported under Visit OI-1 dated 24Feb2021 in PPD Central lab; however Visit OI-1 is blank in EDC. Please reconcile.' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 20:34:17
User opened query 'Per GCL Lab Recon: Sample was reported under Visit OI-1 dated 24Feb2021 in PPD Central lab; however Visit OI-1 is blank in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 02:34:46
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 16:20:51

**US3712271**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '1'	System	19 Nov 2020 16:20:51

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:25', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '166efb98-c622-4a76-9575-8f42244db83a' User entered 'Yes (Y)'	System	19 Nov 2020 16:54:41
	System	19 Nov 2020 16:54:41



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:32', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '166efb98-c622-4a76-9575-8f42244db83a' User entered '99.1'	System	19 Nov 2020 16:54:41
	System	19 Nov 2020 16:54:41

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '166efb98-c622-4a76-9575-8f42244db83a' User entered 'No (N)'	System	19 Nov 2020 16:54:41
	System	19 Nov 2020 16:54:41

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '166efb98-c622-4a76-9575-8f42244db83a' User entered '19 Nov 2020 11:54'	System	19 Nov 2020 16:54:41
	System	19 Nov 2020 16:54:41

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 11:33'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:03'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:26', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '56236f30-5ad4-4240-be95-20b7868a40a0' User entered 'Yes (Y)'	System	20 Nov 2020 02:36:39
	System	20 Nov 2020 02:36:39

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '56236f30-5ad4-4240-be95-20b7868a40a0' User entered '99.2'	System	20 Nov 2020 02:36:39
	System	20 Nov 2020 02:36:39



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '56236f30-5ad4-4240-be95-20b7868a40a0' User entered 'No (N)'	System	20 Nov 2020 02:36:39
	System	20 Nov 2020 02:36:39

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '56236f30-5ad4-4240-be95-20b7868a40a0' User entered '19 Nov 2020 21:36'	System	20 Nov 2020 02:36:39
	System	20 Nov 2020 02:36:39

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:58'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 2'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:01:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '633ce1e3-29ce-4d1c-a8cb-77b31bb00da1' User entered 'Yes (Y)'	System	20 Nov 2020 17:02:24
	System	20 Nov 2020 17:02:24

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:01:49', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '633ce1e3-29ce-4d1c-a8cb-77b31bb00da1' User entered '98.3'	System	20 Nov 2020 17:02:24
	System	20 Nov 2020 17:02:24

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:01:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '633ce1e3-29ce-4d1c-a8cb-77b31bb00da1' User entered 'No (N)'	System	20 Nov 2020 17:02:24
	System	20 Nov 2020 17:02:24



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:01:54', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '633ce1e3-29ce-4d1c-a8cb-77b31bb00da1' User entered '20 Nov 2020 12:01'	System	20 Nov 2020 17:02:24
	System	20 Nov 2020 17:02:24

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:30:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 3'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a1b46ea1-c2cd-45c0-bad8-140f8039ff1e' User entered 'Yes (Y)'	System	22 Nov 2020 07:00:41
	System	22 Nov 2020 07:00:41

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a1b46ea1-c2cd-45c0-bad8-140f8039ff1e' User entered '98.1'	System	22 Nov 2020 07:00:41
	System	22 Nov 2020 07:00:41

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a1b46ea1-c2cd-45c0-bad8-140f8039ff1e' User entered 'No (N)'	System	22 Nov 2020 07:00:41
	System	22 Nov 2020 07:00:41

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a1b46ea1-c2cd-45c0-bad8-140f8039ff1e' User entered '22 Nov 2020 02:00'	System	22 Nov 2020 07:00:41
	System	22 Nov 2020 07:00:41



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 4'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cab27f54-fa6e-451e-a6d8-35c2a12d52a7' User entered 'Yes (Y)'	System	23 Nov 2020 05:08:28
	System	23 Nov 2020 05:08:28

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cab27f54-fa6e-451e-a6d8-35c2a12d52a7' User entered '98.0'	System	23 Nov 2020 05:08:28
	System	23 Nov 2020 05:08:28

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cab27f54-fa6e-451e-a6d8-35c2a12d52a7' User entered 'No (N)'	System	23 Nov 2020 05:08:28
	System	23 Nov 2020 05:08:28

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:25', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cab27f54-fa6e-451e-a6d8-35c2a12d52a7' User entered '23 Nov 2020 00:08'	System	23 Nov 2020 05:08:28
	System	23 Nov 2020 05:08:28

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:30:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 16:22:11



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 5'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T05:59:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9a789ada-8c97-4e9a-bcda-6b270ad8a127' User entered 'Yes (Y)'	System	24 Nov 2020 10:59:46
	System	24 Nov 2020 10:59:46

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T05:59:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9a789ada-8c97-4e9a-bcda-6b270ad8a127' User entered '98.1'	System	24 Nov 2020 10:59:46
	System	24 Nov 2020 10:59:46

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T05:59:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9a789ada-8c97-4e9a-bcda-6b270ad8a127'	System	24 Nov 2020 10:59:46
User entered 'No (N)'	System	24 Nov 2020 10:59:46

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T05:59:43', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9a789ada-8c97-4e9a-bcda-6b270ad8a127' User entered '24 Nov 2020 05:59'	System	24 Nov 2020 10:59:46
	System	24 Nov 2020 10:59:46

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 16:22:11



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 6'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b08d408-9f51-4dd6-96bd-0da7d7f40a0e' User entered 'Yes (Y)'	System	24 Nov 2020 17:31:28
	System	24 Nov 2020 17:31:28

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:20', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b08d408-9f51-4dd6-96bd-0da7d7f40a0e' User entered '98.6'	System	24 Nov 2020 17:31:28
	System	24 Nov 2020 17:31:28

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:22', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b08d408-9f51-4dd6-96bd-0da7d7f40a0e' User entered 'No (N)'	System	24 Nov 2020 17:31:28
	System	24 Nov 2020 17:31:28

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:24', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b08d408-9f51-4dd6-96bd-0da7d7f40a0e' User entered '24 Nov 2020 12:31'	System	24 Nov 2020 17:31:28
	System	24 Nov 2020 17:31:28

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:30:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 7'	System	19 Nov 2020 16:22:11



US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:19', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '09c01ff6-9ed4-4ad8-a05b-0629f94f126d' User entered 'Yes (Y)'	System	25 Nov 2020 17:08:31
	System	25 Nov 2020 17:08:31

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:22', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '09c01ff6-9ed4-4ad8-a05b-0629f94f126d' User entered '99.4'	System	25 Nov 2020 17:08:31
	System	25 Nov 2020 17:08:31

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:24', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '09c01ff6-9ed4-4ad8-a05b-0629f94f126d'	System	25 Nov 2020 17:08:31
User entered 'No (N)'	System	25 Nov 2020 17:08:31

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '09c01ff6-9ed4-4ad8-a05b-0629f94f126d' User entered '25 Nov 2020 12:08'	System	25 Nov 2020 17:08:31
	System	25 Nov 2020 17:08:31

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:30:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '40fce937-d9bc-448a-bcce-4f8191901767' User entered 'None (1)'	System	19 Nov 2020 16:54:51
	System	19 Nov 2020 16:54:51



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '40fce937-d9bc-448a-bcce-4f8191901767'	System	19 Nov 2020 16:54:51
User entered 'No (N)'	System	19 Nov 2020 16:54:51

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '40fce937-d9bc-448a-bcce-4f8191901767'	System	19 Nov 2020 16:54:51
User entered 'No (N)'	System	19 Nov 2020 16:54:51

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:46', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '40fce937-d9bc-448a-bcce-4f8191901767'	System	19 Nov 2020 16:54:51
User entered 'None (1)'	System	19 Nov 2020 16:54:51

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '40fce937-d9bc-448a-bcce-4f8191901767' User entered '19 Nov 2020 11:54'	System	19 Nov 2020 16:54:51
	System	19 Nov 2020 16:54:51

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 11:33'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:03'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '37f24ac4-f5dc-4dde-8045-37ef993e69ba' User entered 'None (1)'	System	20 Nov 2020 02:36:50
	System	20 Nov 2020 02:36:50



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '37f24ac4-f5dc-4dde-8045-37ef993e69ba' User entered 'No (N)'	System	20 Nov 2020 02:36:50
	System	20 Nov 2020 02:36:50

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:43', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '37f24ac4-f5dc-4dde-8045-37ef993e69ba' User entered 'No (N)'	System	20 Nov 2020 02:36:50
	System	20 Nov 2020 02:36:50

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '37f24ac4-f5dc-4dde-8045-37ef993e69ba' User entered 'None (1)'	System	20 Nov 2020 02:36:50
	System	20 Nov 2020 02:36:50

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '37f24ac4-f5dc-4dde-8045-37ef993e69ba' User entered '19 Nov 2020 21:36'	System	20 Nov 2020 02:36:50
	System	20 Nov 2020 02:36:50

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:58'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 2'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '38692907-12fd-4d3f-b9e4-f18430a545e5' User entered 'None (1)'	System	20 Nov 2020 17:02:40
	System	20 Nov 2020 17:02:40



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '38692907-12fd-4d3f-b9e4-f18430a545e5' User entered 'No (N)'	System	20 Nov 2020 17:02:40
	System	20 Nov 2020 17:02:40

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '38692907-12fd-4d3f-b9e4-f18430a545e5' User entered 'No (N)'	System	20 Nov 2020 17:02:40
	System	20 Nov 2020 17:02:40

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '38692907-12fd-4d3f-b9e4-f18430a545e5' User entered 'None (1)'	System	20 Nov 2020 17:02:40
	System	20 Nov 2020 17:02:40

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '38692907-12fd-4d3f-b9e4-f18430a545e5' User entered '20 Nov 2020 12:02'	System	20 Nov 2020 17:02:40
	System	20 Nov 2020 17:02:40

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 3'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a40e83af-3694-4929-a4d2-29ec6f643053' User entered 'None (1)'	System	22 Nov 2020 07:00:54
	System	22 Nov 2020 07:00:54



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:46', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a40e83af-3694-4929-a4d2-29ec6f643053' User entered 'No (N)'	System	22 Nov 2020 07:00:54
	System	22 Nov 2020 07:00:54

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a40e83af-3694-4929-a4d2-29ec6f643053'	System	22 Nov 2020 07:00:54
User entered 'No (N)'	System	22 Nov 2020 07:00:54

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:49', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a40e83af-3694-4929-a4d2-29ec6f643053' User entered 'None (1)'	System	22 Nov 2020 07:00:54
	System	22 Nov 2020 07:00:54

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:51', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a40e83af-3694-4929-a4d2-29ec6f643053' User entered '22 Nov 2020 02:00'	System	22 Nov 2020 07:00:54
	System	22 Nov 2020 07:00:54

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 4'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:28', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc8b2e48-761a-464f-83f4-c519f58fe1e7'	System	23 Nov 2020 05:08:39
User entered 'None (1)'	System	23 Nov 2020 05:08:39



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:30', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc8b2e48-761a-464f-83f4-c519f58fe1e7' User entered 'No (N)'	System	23 Nov 2020 05:08:39
	System	23 Nov 2020 05:08:39

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc8b2e48-761a-464f-83f4-c519f58fe1e7' User entered 'No (N)'	System	23 Nov 2020 05:08:39
	System	23 Nov 2020 05:08:39

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:33', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc8b2e48-761a-464f-83f4-c519f58fe1e7' User entered 'None (1)'	System	23 Nov 2020 05:08:39
	System	23 Nov 2020 05:08:39

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc8b2e48-761a-464f-83f4-c519f58fe1e7' User entered '23 Nov 2020 00:08'	System	23 Nov 2020 05:08:39
	System	23 Nov 2020 05:08:39

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 5'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:18', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a3babc82-5df1-444c-b2f7-d1872692f1d4' User entered 'None (1)'	System	24 Nov 2020 11:00:32
	System	24 Nov 2020 11:00:32



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:20', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a3babc82-5df1-444c-b2f7-d1872692f1d4' User entered 'No (N)'	System	24 Nov 2020 11:00:32
	System	24 Nov 2020 11:00:32

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a3babc82-5df1-444c-b2f7-d1872692f1d4' User entered 'No (N)'	System	24 Nov 2020 11:00:32
	System	24 Nov 2020 11:00:32

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a3babc82-5df1-444c-b2f7-d1872692f1d4' User entered 'None (1)'	System	24 Nov 2020 11:00:32
	System	24 Nov 2020 11:00:32

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:28', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'a3babc82-5df1-444c-b2f7-d1872692f1d4' User entered '24 Nov 2020 06:00'	System	24 Nov 2020 11:00:32
	System	24 Nov 2020 11:00:32

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 6'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'f6201149-9035-4378-9df0-c4d66648de5e' User entered 'None (1)'	System	24 Nov 2020 17:31:38
	System	24 Nov 2020 17:31:38



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:29', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'f6201149-9035-4378-9df0-c4d66648de5e' User entered 'No (N)'	System	24 Nov 2020 17:31:38
	System	24 Nov 2020 17:31:38

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:30', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'f6201149-9035-4378-9df0-c4d66648de5e' User entered 'No (N)'	System	24 Nov 2020 17:31:38
	System	24 Nov 2020 17:31:38

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'f6201149-9035-4378-9df0-c4d66648de5e' User entered 'None (1)'	System	24 Nov 2020 17:31:38
	System	24 Nov 2020 17:31:38

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:35', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'f6201149-9035-4378-9df0-c4d66648de5e' User entered '24 Nov 2020 12:31'	System	24 Nov 2020 17:31:38
	System	24 Nov 2020 17:31:38

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 7'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:30', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3286c833-9826-49c9-b6fb-4095ab09600e' User entered 'None (1)'	System	25 Nov 2020 17:08:42
	System	25 Nov 2020 17:08:42



US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:32', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3286c833-9826-49c9-b6fb-4095ab09600e' User entered 'No (N)'	System	25 Nov 2020 17:08:42
	System	25 Nov 2020 17:08:42

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3286c833-9826-49c9-b6fb-4095ab09600e' User entered 'No (N)'	System	25 Nov 2020 17:08:42
	System	25 Nov 2020 17:08:42

US3712271

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:38', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3286c833-9826-49c9-b6fb-4095ab09600e' User entered 'None (1)'	System	25 Nov 2020 17:08:42
	System	25 Nov 2020 17:08:42

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3286c833-9826-49c9-b6fb-4095ab09600e' User entered '25 Nov 2020 12:08'	System	25 Nov 2020 17:08:42
	System	25 Nov 2020 17:08:42

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:51', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:54', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:56', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:54:58', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'None (0)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:55:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered 'No (N)'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T11:55:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '584f15e9-6a53-4df0-a765-61591ea927cd' User entered '19 Nov 2020 11:55'	System	19 Nov 2020 16:55:09
	System	19 Nov 2020 16:55:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 11:33'	System	19 Nov 2020 16:22:11



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:03'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:54', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:55', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:36:59', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:37:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'None (0)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09



US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:37:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered 'No (N)'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-19T21:37:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e87fda28-940e-4a0e-8b66-2a7f771933b4' User entered '19 Nov 2020 21:37'	System	20 Nov 2020 02:37:09
	System	20 Nov 2020 02:37:09

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '19 Nov 2020 14:58'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 2'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:10', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:11', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:13', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57



US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:14', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:15', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'None (0)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:19', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered 'No (N)'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-20T12:02:21', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9b4903f5-71c2-47c9-b42f-9a2b7687ec45' User entered '20 Nov 2020 12:02'	System	20 Nov 2020 17:02:57
	System	20 Nov 2020 17:02:57

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 3'	System	19 Nov 2020 16:22:11



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:55', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:56', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:00:58', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:01:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:01:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'None (0)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:01:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered 'No (N)'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-22T02:01:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'ea9cbf55-3e6a-4d1b-acfe-ae3dfb466d7d' User entered '22 Nov 2020 02:01'	System	22 Nov 2020 07:01:07
	System	22 Nov 2020 07:01:07



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 4'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:39', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'None (0)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:49', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered 'No (N)'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-23T00:08:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e5dbccda-3092-4726-8814-a25cb5b290ae' User entered '23 Nov 2020 00:08'	System	23 Nov 2020 05:08:56
	System	23 Nov 2020 05:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 5'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48



US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:39', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:40', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:42', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'None (0)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered 'No (N)'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T06:00:46', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '16eeadbe-cea8-44bc-9fbb-775887f5ec9f' User entered '24 Nov 2020 06:00'	System	24 Nov 2020 11:00:48
	System	24 Nov 2020 11:00:48

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 16:22:11



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 6'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:54', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:56', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:31:57', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'None (0)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:32:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered 'No (N)'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-24T12:32:02', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c3e6a870-84e2-4a9a-a6ec-6d5ef7b7cf1a' User entered '24 Nov 2020 12:32'	System	24 Nov 2020 17:32:04
	System	24 Nov 2020 17:32:04

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
Data entry locked.	System	19 Nov 2020 16:22:11
User entered 'Day 7'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:43', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:44', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:45', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56



**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:49', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'None (0)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

US3712271

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:30:02

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 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered 'No (N)'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-11-25T12:08:53', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '7937e4c5-d413-4bec-9351-d0047b02739f' User entered '25 Nov 2020 12:08'	System	25 Nov 2020 17:08:56
	System	25 Nov 2020 17:08:56

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:30:02**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:59:20
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 16:22:11

**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:25

**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:25



**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:25

**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:55:25

**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:41:29

**US3712271**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'I'	System	10 Dec 2020 21:41:29

US3712271

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 24-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	25 Mar 2021 08:03:08
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 24-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	22 Mar 2021 20:33:34
' answered with 'updating' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 24-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	08 Mar 2021 05:01:28
' (Site from DM). User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 21:42:50

**US3712271**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:42:50

**US3712271**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:42:50

**US3712271**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:42:50



US3712271

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 20:41:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:42:52

**US3712271**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'I'	System	10 Dec 2020 21:42:52

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:29

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:29

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:29

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:29

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:31

**US3712271**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'I'	System	23 Mar 2021 19:30:31



**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:36

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:36

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:36

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered 'VISIT3'	System	23 Mar 2021 19:30:36

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:39



**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39



**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:39

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:39

US3712271

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21

US3712271

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:41

US3712271

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:41

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:43



**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:43

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:43

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered empty.	System	23 Mar 2021 19:30:43

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:30:46

**US3712271**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:21
User entered '1'	System	23 Mar 2021 19:30:46

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:18', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered 'Yes (Y)'	System	19 Dec 2020 11:08:15
	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:23', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered 'Yes (Y)'	System	19 Dec 2020 11:08:15
	System	19 Dec 2020 11:08:15



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Please 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:30', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1'	System	19 Dec 2020 11:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:36', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered 'Yes (Y)'	System	19 Dec 2020 11:08:15
	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '0'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '0'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '1'	System	19 Dec 2020 11:08:15



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '0'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '0'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:50', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '0'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Please 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:07:54', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1'	System	19 Dec 2020 11:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:08:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1'	System	19 Dec 2020 11:08:15
User entered 'Yes (Y)'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Please 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:08:03', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1'	System	19 Dec 2020 11:08:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-19T06:08:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'e1ffc513-9f3c-47e4-9f49-422a1d9877f1' User entered '19 Dec 2020 06:08:06'	System	19 Dec 2020 11:08:15
	System	19 Dec 2020 11:08:15

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-26T14:53:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fc7104d0-7d8b-4a97-a74f-a4e650ccb329' User entered 'No (N)'	System	26 Dec 2020 19:53:18
	System	26 Dec 2020 19:53:18

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-26T14:53:12', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fc7104d0-7d8b-4a97-a74f-a4e650ccb329' User entered 'No (N)'	System	26 Dec 2020 19:53:18

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2020-12-26T14:53:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'fc7104d0-7d8b-4a97-a74f-a4e650ccb329' User entered '26 Dec 2020 14:53:16'	System	26 Dec 2020 19:53:18
	System	26 Dec 2020 19:53:18

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:10:56



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-02T00:02:12', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'dee16532-b114-417a-9b61-dbd9ffcd6ba'	System	02 Jan 2021 05:02:49
User entered 'No (N)'	System	02 Jan 2021 05:02:49

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-02T00:02:13', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'dee16532-b114-417a-9b61-dbd9ffcda6ba'	System	02 Jan 2021 05:02:49
User entered 'No (N)'	System	02 Jan 2021 05:02:49

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-02T00:02:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'dee16532-b114-417a-9b61-dbd9ffcda6ba' User entered '02 Jan 2021 00:02:16'	System	02 Jan 2021 05:02:49
	System	02 Jan 2021 05:02:49

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-09T21:11:48', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c54db3c-ddae-403f-b2f5-9baa3e3355ab' User entered 'No (N)'	System	10 Jan 2021 02:11:58
	System	10 Jan 2021 02:11:58

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-09T21:11:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c54db3c-ddae-403f-b2f5-9baa3e3355ab'	System	10 Jan 2021 02:11:58
User entered 'No (N)'	System	10 Jan 2021 02:11:58



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-09T21:11:56', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9c54db3c-ddae-403f-b2f5-9baa3e3355ab' User entered '09 Jan 2021 21:11:56'	System	10 Jan 2021 02:11:58
	System	10 Jan 2021 02:11:58

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-16T13:46:11', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '595471a3-20d2-4938-a1f1-4046b26bb724'	System	16 Jan 2021 18:46:20
User entered 'No (N)'	System	16 Jan 2021 18:46:20

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-16T13:46:14', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '595471a3-20d2-4938-a1f1-4046b26bb724'	System	16 Jan 2021 18:46:20
User entered 'No (N)'	System	16 Jan 2021 18:46:20

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-16T13:46:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '595471a3-20d2-4938-a1f1-4046b26bb724'	System	16 Jan 2021 18:46:20
User entered '16 Jan 2021 13:46:16'	System	16 Jan 2021 18:46:20

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-26T18:00:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9d29c565-0db1-41ab-97b7-729adbefb92e'	System	27 Jan 2021 00:38:14
User entered 'No (N)'	System	27 Jan 2021 00:38:14

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-26T18:00:09', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9d29c565-0db1-41ab-97b7-729adbefb92e'	System	27 Jan 2021 00:38:14
User entered 'No (N)'	System	27 Jan 2021 00:38:14

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-26T18:00:13', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '9d29c565-0db1-41ab-97b7-729adbefb92e' User entered '26 Jan 2021 18:00:13'	System	27 Jan 2021 00:38:14
	System	27 Jan 2021 00:38:14

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:10:56



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-31T01:04:26', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '35310dfe-ad42-48e7-bf4b-72e1743655e3' User entered 'No (N)'	System	31 Jan 2021 06:04:35
	System	31 Jan 2021 06:04:35

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-31T01:04:28', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '35310dfe-ad42-48e7-bf4b-72e1743655e3'	System	31 Jan 2021 06:04:35
User entered 'No (N)'	System	31 Jan 2021 06:04:35

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-01-31T01:04:31', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '35310dfe-ad42-48e7-bf4b-72e1743655e3' User entered '31 Jan 2021 01:04:31'	System	31 Jan 2021 06:04:35
	System	31 Jan 2021 06:04:35

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-06T09:16:49', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c48ff13e-aac0-4ab3-b0df-d279e4a8754d' User entered 'No (N)'	System	06 Feb 2021 14:16:57
	System	06 Feb 2021 14:16:57

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-06T09:16:52', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c48ff13e-aac0-4ab3-b0df-d279e4a8754d' User entered 'No (N)'	System	06 Feb 2021 14:16:57



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-06T09:16:55', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c48ff13e-aac0-4ab3-b0df-d279e4a8754d' User entered '06 Feb 2021 09:16:55'	System	06 Feb 2021 14:16:57
	System	06 Feb 2021 14:16:57

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:10:56

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-16T04:52:26', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '4bffbcc3-1400-4dde-b0b6-03116ee68a1f' User entered 'No (N)'	System	16 Feb 2021 09:52:32

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-16T04:52:27', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '4bffbcc3-1400-4dde-b0b6-03116ee68a1f' User entered 'No (N)'	System	16 Feb 2021 09:52:32

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-16T04:52:29', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '4bffbcc3-1400-4dde-b0b6-03116ee68a1f' User entered '16 Feb 2021 04:52:29'	System	16 Feb 2021 09:52:32

**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-24T10:38:04', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '55fcecdd-c327-40d2-b5c1-3414ada5a185' User entered 'No (N)'	System	24 Feb 2021 15:38:12

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-24T10:38:06', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '55fcecdd-c327-40d2-b5c1-3414ada5a185'	System	24 Feb 2021 15:38:12
User entered 'No (N)'	System	24 Feb 2021 15:38:12

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-24T10:38:08', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '55fcecdd-c327-40d2-b5c1-3414ada5a185' User entered '24 Feb 2021 10:38:08'	System	24 Feb 2021 15:38:12
	System	24 Feb 2021 15:38:12

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:49:34', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered 'Yes (Y)'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:49:37', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered 'No (N)'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:49:47', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered 'Yes (Y)'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '1'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '1'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '1'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '1'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '1'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '0'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Please 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:07', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b'	System	27 Feb 2021 08:50:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:13', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered 'No (N)'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-02-27T03:50:16', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '20cbea6e-b0ae-4137-95d6-6e88aed4609b' User entered '27 Feb 2021 03:50:16'	System	27 Feb 2021 08:50:27
	System	27 Feb 2021 08:50:27

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-15T12:30:12-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8a804937-ce07-47a1-ac19-7e90f3f33fbc'	System	15 Mar 2021 16:30:24
User entered 'No (N)'	System	15 Mar 2021 16:30:24

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-15T12:30:15-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8a804937-ce07-47a1-ac19-7e90f3f33fbc'	System	15 Mar 2021 16:30:24
User entered 'No (N)'	System	15 Mar 2021 16:30:24

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-15T12:30:18-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '8a804937-ce07-47a1-ac19-7e90f3f33fbc' User entered '15 Mar 2021 12:30:18'	System	15 Mar 2021 16:30:24
	System	15 Mar 2021 16:30:24



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-22T12:29:01-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c7036b05-5b37-42d9-8d87-043a6ea83acc'	System	22 Mar 2021 16:49:29
User entered 'No (N)'	System	22 Mar 2021 16:49:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-22T12:29:02-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c7036b05-5b37-42d9-8d87-043a6ea83acc'	System	22 Mar 2021 16:49:29
User entered 'No (N)'	System	22 Mar 2021 16:49:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-22T12:29:04-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'c7036b05-5b37-42d9-8d87-043a6ea83acc'	System	22 Mar 2021 16:49:29
User entered '22 Mar 2021 12:29:04'	System	22 Mar 2021 16:49:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-28T11:19:15-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc785ffc-5c49-4a91-b01f-f2a03a4f530f' User entered 'No (N)'	System	28 Mar 2021 15:19:24

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-28T11:19:17-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc785ffc-5c49-4a91-b01f-f2a03a4f530f'	System	28 Mar 2021 15:19:24
User entered 'No (N)'	System	28 Mar 2021 15:19:24

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-28T11:19:20-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'cc785ffc-5c49-4a91-b01f-f2a03a4f530f' User entered '28 Mar 2021 11:19:20'	System	28 Mar 2021 15:19:24
	System	28 Mar 2021 15:19:24

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-05T12:00:10-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0d3be5b3-b368-43e8-bc65-22b8982f1bbf' User entered 'No (N)'	System	05 Apr 2021 16:00:22
	System	05 Apr 2021 16:00:22



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-05T12:00:12-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0d3be5b3-b368-43e8-bc65-22b8982f1bbf' User entered 'No (N)'	System	05 Apr 2021 16:00:22
	System	05 Apr 2021 16:00:22

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-05T12:00:14-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '0d3be5b3-b368-43e8-bc65-22b8982f1bbf' User entered '05 Apr 2021 12:00:14'	System	05 Apr 2021 16:00:22
	System	05 Apr 2021 16:00:22

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-13T18:04:50-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '919b0364-9d13-46dc-8e47-7abf7852624b'	System	13 Apr 2021 22:07:29
User entered 'No (N)'	System	13 Apr 2021 22:07:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-13T18:04:51-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '919b0364-9d13-46dc-8e47-7abf7852624b' User entered 'No (N)'	System	13 Apr 2021 22:07:29
	System	13 Apr 2021 22:07:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-13T18:04:53-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '919b0364-9d13-46dc-8e47-7abf7852624b'	System	13 Apr 2021 22:07:29
User entered '13 Apr 2021 18:04:53'	System	13 Apr 2021 22:07:29



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-17T15:51:44-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'adf19705-d341-4117-8f53-786181c2fea9'	System	17 Apr 2021 19:51:50
User entered 'No (N)'	System	17 Apr 2021 19:51:50

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-17T15:51:46-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'adf19705-d341-4117-8f53-786181c2fea9'	System	17 Apr 2021 19:51:50
User entered 'No (N)'	System	17 Apr 2021 19:51:50

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-17T15:51:47-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'adf19705-d341-4117-8f53-786181c2fea9' User entered '17 Apr 2021 15:51:47'	System	17 Apr 2021 19:51:50
	System	17 Apr 2021 19:51:50

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-26T18:41:21-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '51e4fd29-6c5c-427a-99d1-f545fbfb4d9'	System	26 Apr 2021 22:41:29
User entered 'No (N)'	System	26 Apr 2021 22:41:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-26T18:41:23-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '51e4fd29-6c5c-427a-99d1-f545fbfb4d9'	System	26 Apr 2021 22:41:29
User entered 'No (N)'	System	26 Apr 2021 22:41:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-04-26T18:41:26-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '51e4fd29-6c5c-427a-99d1-f545fbfbb4d9'	System	26 Apr 2021 22:41:29
User entered '26 Apr 2021 18:41:26'	System	26 Apr 2021 22:41:29

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-05-01T08:51:21-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3be4f3ef-be99-4bf4-82e1-2af8ff501427'	System	01 May 2021 12:51:31
User entered 'No (N)'	System	01 May 2021 12:51:31



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Have you been exposed to someone with 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 (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-05-01T08:51:22-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3be4f3ef-be99-4bf4-82e1-2af8ff501427'	System	01 May 2021 12:51:31
User entered 'No (N)'	System	01 May 2021 12:51:31

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-05-01T08:51:25-04:00', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: '3be4f3ef-be99-4bf4-82e1-2af8ff501427'	System	01 May 2021 12:51:31
User entered '01 May 2021 08:51:25'	System	01 May 2021 12:51:31

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 13:10:56



**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:10:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 13:10:56

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 13:10:56



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '24 Dec 2022 00:01'	System	20 Nov 2020 13:10:56

**US3712271**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:30:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:10:56
Amendment Manager: User entered '28 Dec 2022 23:59'	System	20 Nov 2020 13:10:56

US3712271

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:30:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-01T21:24:01', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'daeda2ed-8712-4e00-b8e8-e748750cc3f1'	System	02 Mar 2021 02:31:39
User entered 'No (N)'	System	02 Mar 2021 02:31:39

**US3712271**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:29:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0A7875B-7BBD-4ECE-B438-501074F71B09)', Time: '2021-03-01T21:24:05', User OID: 'PatientReportedOutcome (US3712271)', ODM File OID: 'daeda2ed-8712-4e00-b8e8-e748750cc3f1' User entered '01 Mar 2021 21:24:05'	System	02 Mar 2021 02:31:39
	System	02 Mar 2021 02:31:39



**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:36

**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:36

**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:36

**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:36

**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:52:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:40

**US3712271**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:27
User entered 'I'	System	23 Mar 2021 19:31:40

**US3712271**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:45

**US3712271**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:45



**US3712271**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:45

**US3712271**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:31:45

US3712271

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Mar 2021 19:31:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 19:31:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 19:31:52
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:31:48
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:31:48

**US3712271**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User entered 'I'	System	23 Mar 2021 19:31:52
User entered empty.	System	23 Mar 2021 19:31:48

**US3712271**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:36:12

US3712271

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	30 Mar 2021 18:36:15
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	30 Mar 2021 18:36:15
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:36:15
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	30 Mar 2021 18:36:12
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:36:12

**US3712271**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:36:12

**US3712271**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:36:12



**US3712271**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:36:17

**US3712271**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:17:26
User entered '1'	System	30 Mar 2021 18:36:17

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:25
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:43:10
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:01:46

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Time of contact seems to be 12:04 on 14Dec2020 when patient initiated contact with the site. If confirmed, consider updating.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:41:20
Query 'Time of contact seems to be 12:04 on 14Dec2020 when patient initiated contact with the site. If confirmed, consider updating.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:41:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:41:18
User entered '12:04' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:43:10
User opened query 'Time of contact seems to be 12:04 on 14Dec2020 when patient initiated contact with the site. If confirmed, consider updating.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:42:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Dec 2020 15:01:53
User entered '13:15' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 15:01:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Dec 2020 15:01:46
User entered '13:' (non-conformant).	(b) (4), (b) (6)	15 Dec 2020 15:01:46

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:25
User entered '14 Dec 2020 12:04'	System	09 Feb 2021 17:41:18
User entered '14 Dec 2020 13:15'	System	15 Dec 2020 15:01:53
User entered '14 Dec 2020 13:' (non-conformant).	System	15 Dec 2020 15:01:46

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:02

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:04:21
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Per eCRF guidelines, if patient contacts site to report Covid19 symptoms, this should be noted as "safety contact"' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:41:22
Query 'Per eCRF guidelines, if patient contacts site to report Covid19 symptoms, this should be noted as "safety contact"' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:41:29
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:41:18
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:43:10
User opened query 'Per eCRF guidelines, if patient contacts site to report Covid19 symptoms, this should be noted as "safety contact"' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:42:42
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	15 Dec 2020 15:01:46

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:25
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:43:10
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 15:01:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 15:01:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 15:01:53
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 15:01:46
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:01:46

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '11 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:13:14
User closed query 'Per CDM : Please check from log line 1-3.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done. '(Site from DM).	(b) (4), (b) (6)	18 Jan 2021 19:12:05
Query 'Per CDM : Please check from log line 1-3.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done.	(b) (4), (b) (6)	13 Jan 2021 20:12:59
' answered with 'UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:12:54
User opened query 'Per CDM : Please check from log line 1-3.It appears that O2 saturation and Temperature was not collected. If not collected, please consider recording it as Not Done. '(Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:06:24
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	13 Jan 2021 20:12:54
User entered empty.	System	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	13 Jan 2021 20:13:34
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:24:18
User entered 'Mild (Mild)' reason for change: Data Entry Error		09 Feb 2021 17:24:18
DataPoint Verified.		26 Jan 2021 22:13:14
User entered 'None (None)'		15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:04:24

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '12 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 15:05:19



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	13 Jan 2021 20:13:12
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	13 Jan 2021 20:13:12
User entered empty.	System	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	13 Jan 2021 20:13:12
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:24:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:24:10
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:05:19

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '13 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	13 Jan 2021 20:13:19
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	13 Jan 2021 20:13:19
User entered empty.	System	15 Dec 2020 15:06:12



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	13 Jan 2021 20:13:19
change Data Entry Error		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User closed query 'Please confirm, as initial covid contact, 11Dec2020 was noted; however, on the symptom log and Illness Visit 1, 13Dec2020 was noted. Please confirm correct date and update whichever source is necessary.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:43:10
Query 'Please confirm, as initial covid contact, 11Dec2020 was noted; however, on the symptom log and Illness Visit 1, 13Dec2020 was noted. Please confirm correct date and update whichever source is necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:24:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm, as initial covid contact, 11Dec2020 was noted; however, on the symptom log and Illness Visit 1, 13Dec2020 was noted. Please confirm correct date and update whichever source is necessary.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:31:37
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:12

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:32:58
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	17 Dec 2020 16:32:58
User entered empty.	System	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '37.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:32:58
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 15:06:47

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '15 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:30:25
User closed query 'Please confirm as source indicates 97. If confirmed, please update, or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:22
Query 'Please confirm as source indicates 97. If confirmed, please update, or clarify otherwise.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:24:59
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:24:52
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:24:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm as source indicates 97. If confirmed, please update, or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:37:29
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:31:24
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	17 Dec 2020 16:31:24
User entered empty.	System	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:30
User closed query 'Please confirm, as source seems to indicate 100.7. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:28
Query 'Please confirm, as source seems to indicate 100.7. If confirmed, please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:25:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:24:52
User entered '100.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:24:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm, as source seems to indicate 100.7. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:39:06
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:31:24
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:29:31

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '16 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	17 Dec 2020 16:30:28



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:31:06
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 16:30:28

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	17 Dec 2020 16:31:06
User entered empty.	System	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:46
User closed query 'Please confirm as source notes 99.9. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:44
Query 'Please confirm as source notes 99.9. If confirmed, please update or clarify otherwise.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:25:24
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:25:19
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:25:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm as source notes 99.9. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:45:13
User entered '100.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:31:06
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 16:30:28

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:30:55
User closed query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:53
Query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:25:37
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:25:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:25:33
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:45:51
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:30:59
User closed query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:30:58
Query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:25:41
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:25:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:25:33
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm, as "none" seems to be noted in source. If confirmed, please update or clarify otherwise' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:46:05
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:30:28

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '98'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	17 Dec 2020 16:33:59



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '100.0' F	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	17 Dec 2020 16:33:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '18 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '98'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '101.4' F	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:33:52

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '19 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:05:07
User closed query 'This should be the lowest recorded measurement which per source was 92% ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:05:04
Query 'This should be the lowest recorded measurement which per source was 92% ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:17:24
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:17:14
User opened query 'This should be the lowest recorded measurement which per source was 92% ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:51:12
User closed query 'Please ensure the PI reviews this saturation rate, as it is below 93% per protocol' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:51:12
Query 'Please ensure the PI reviews this saturation rate, as it is below 93% per protocol' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:26:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:26:40
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:26:40
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please ensure the PI reviews this saturation rate, as it is below 93% per protocol' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:53:08
User entered '92'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '100.3' F	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:36:59

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '20 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 20:38:55



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
	(b) (4), (b) (6)	
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:52:22
User closed query 'Please confirm, as the lowest value should be entered, which appears to be 92% per source. If confirmed, please update. PI / Subi should review and assess this value per protocol.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:52:21
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:28:21
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:28:21
Query 'Please confirm, as the lowest value should be entered, which appears to be 92% per source. If confirmed, please update. PI / Subi should review and assess this value per protocol.' answered with 'updating' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:28:18
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm, as the lowest value should be entered, which appears to be 92% per source. If confirmed, please update. PI / Subi should review and assess this value per protocol.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:56:46
User entered '98'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '101.4' F	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:38:55

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:05:34
User closed query 'Subject went to ER/was admitted to hospital on this date and in the hospital notes page 11 of 121, notes patient reported O2 dropped to the 80's. Please review with subject and update as needed.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:05:32
Query 'Subject went to ER/was admitted to hospital on this date and in the hospital notes page 11 of 121, notes patient reported O2 dropped to the 80's. Please review with subject and update as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 12:24:30
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 12:24:14
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 12:24:14
User opened query 'Subject went to ER/was admitted to hospital on this date and in the hospital notes page 11 of 121, notes patient reported O2 dropped to the 80's. Please review with subject and update as needed.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:15:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '94'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	22 Dec 2020 20:40:18



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:15:02
User closed query 'Please confirm with source units, as 102.4 Celsius is abnormal and not expected. Please reconcile and update units as needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:42:14
Query 'Please confirm with source units, as 102.4 Celsius is abnormal and not expected. Please reconcile and update units as needed. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:15:35
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:15:28
User entered '102.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:15:28
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Please confirm with source units, as 102.4 Celsius is abnormal and not expected. Please reconcile and update units as needed. ' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:00:47
User closed query 'Per CDM: It appears temperature of 102.4 C is rather high. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:11:08
Query 'Per CDM: It appears temperature of 102.4 C is rather high. Please review and update accordingly.' answered with 'confirmed' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 20:11:27
User opened query 'Per CDM: It appears temperature of 102.4 C is rather high. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 22:33:07
User entered '102.4' C	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:07:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 22:42:30
User closed query 'Per notes in source documents, subject reported difficulty breathing and went to the ER, then admitted to the hospital. Would Only Mild be noted at this time, please review and update or clarify.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:42:29
Query 'Per notes in source documents, subject reported difficulty breathing and went to the ER, then admitted to the hospital. Would Only Mild be noted at this time, please review and update or clarify.' answered with 'confirmed ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:23:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'Per notes in source documents, subject reported difficulty breathing and went to the ER, then admitted to the hospital. Would Only Mild be noted at this time, please review and update or clarify.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:03:45
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	22 Dec 2020 20:40:18

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User closed query 'Per source symptoms persist on 23Dec2020 - 30Dec2020. Please add all symptom logs.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 04:22:11
Query 'Per source symptoms persist on 23Dec2020 - 30Dec2020. Please add all symptom logs.' answered with 'adding' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:28:48
User opened query 'Per source symptoms persist on 23Dec2020 - 30Dec2020. Please add all symptom logs.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:14:23
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '22 Dec 2020'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '97'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	13 Jan 2021 20:12:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered '99.0' F	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User closed query 'As per the prior notes, subject reported difficulty breathing and went to the ER. Please review Difficulty Breathing and Shortness of Breath severity and update as needed or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:07:29
Query 'As per the prior notes, subject reported difficulty breathing and went to the ER. Please review Difficulty Breathing and Shortness of Breath severity and update as needed or clarify otherwise.' answered with 'confirmed' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:28:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User opened query 'As per the prior notes, subject reported difficulty breathing and went to the ER. Please review Difficulty Breathing and Shortness of Breath severity and update as needed or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:05:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:13:14
User entered 'None (None)'	(b) (4), (b) (6)	13 Jan 2021 20:12:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '23 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '96'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '99.2' F	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:30:33

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '24 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:31:07



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '98'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:31:07

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '98.0' F	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '25 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '98'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:31:43



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '98.0' F	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:31:43

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '26 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '100'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '97.2' F	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:15

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '27 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '100'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '98.1' F	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:32:42

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '28 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:33:07



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '100'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '97.0' F	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07



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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:07

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '29 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '100'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:33:53



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '97.4' F	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:33:53

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '30 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '100'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User entered '%'	System	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered '97.1' F	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 09:30:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:33
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 17:34:29

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:30:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:07:22



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:30:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:30:02

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:17:57
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 10:37:47
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 20:04:52
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:04:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:04:45
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	13 Jan 2021 20:04:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:04:45
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 15:07:22
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered 'Nasal Swab (Nasal Swab)'	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:30:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:07:22

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Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:17:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:07:22



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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:37
User entered 'I'	System	13 Jan 2021 20:04:45

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:49
User closed query ' Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:13:40
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Query ' Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:08:36
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:08:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:08:29
User opened query ' Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:52:03
User closed query 'Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:52:03
Query 'Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values.' answered with 'updating' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:43:17
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User opened query 'Please confirm as 92 was noted on 19Dec2020 and 20Dec2020. If confirmed, ensure PI / Sub-I reviews and assess these values.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:32:50
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:57
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:08:29
User entered '19 Dec 2020' reason for change: Data Entry Error		25 Feb 2021 19:08:29
DataPoint Verified.		26 Jan 2021 22:33:11
User entered empty.		13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:44:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:19:58
User closed query 'Subject had 80% while in hospital on 21Dec2020. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:19:52
Query 'Subject had 80% while in hospital on 21Dec2020. Please review and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:13:33
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 19:12:02
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:12:02
User opened query 'Subject had 80% while in hospital on 21Dec2020. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:14:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:08:29
User entered '20 Dec 2020' reason for change: Data Entry Error		25 Feb 2021 19:08:29
DataPoint Verified.		26 Jan 2021 22:33:11
User entered empty.		13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:44:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:19:55
User closed query 'subject had 80% while in hospital on 21Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:19:53
Query 'subject had 80% while in hospital on 21Dec2020. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:13:57
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 19:12:02
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:12:02
User opened query 'subject had 80% while in hospital on 21Dec2020. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:15:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:08:29
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:08:29
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38



US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:30:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 22:33:11
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:05:38

US3712271

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:30:02

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:12:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:15:21
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:35:41

US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:30:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
Query 'Per CRA review of source, saliva was collected on 18Dec and 25Dec2020 only. However, PPD labs have 3 results. Please confirm dates of collection and update as needed or clarify in PPD labs.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:57:54
User opened query 'Per CRA review of source, saliva was collected on 18Dec and 25Dec2020 only. However, PPD labs have 3 results. Please confirm dates of collection and update as needed or clarify in PPD labs.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:34:40
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:30:02

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:56:58
User closed query 'Per CRA review of source, a saliva sample was collected on 18Dec, which seems to correspond to day 5, not day 3. If confirmed, please update. Additionally, PPD labs seems to have resulted 3 tests; however, these are not shown as being collected in source. Subject was hospitalized and many samples were not collected as such. Please review and revise as needed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 21:56:56
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:42:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:42:46
Query 'Per CRA review of source, a saliva sample was collected on 18Dec, which seems to correspond to day 5, not day 3. If confirmed, please update. Additionally, PPD labs seems to have resulted 3 tests; however, these are not shown as being collected in source. Subject was hospitalized and many samples were not collected as such. Please review and revise as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:42:38
User opened query 'Per CRA review of source, a saliva sample was collected on 18Dec, which seems to correspond to day 5, not day 3. If confirmed, please update. Additionally, PPD labs seems to have resulted 3 tests; however, these are not shown as being collected in source. Subject was hospitalized and many samples were not collected as such. Please review and revise as needed.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:00:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:50:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:48:26
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 21:57:00
DataPoint Un-verified.		09 Feb 2021 17:42:46
User entered empty; reason for change Data Entry Error		09 Feb 2021 17:42:46
DataPoint Verified.		27 Jan 2021 14:50:52
User entered '18 Dec 2020' reason for change: Data Entry Error		22 Jan 2021 20:48:26
User entered empty.		13 Jan 2021 20:10:50



US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:30:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 18Dec2020 is reported under Illness Visit Day 5 in EDC, however same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:11:43
Query 'Per GCL Lab Recon: Saliva: Sample dated 18Dec2020 is reported under Illness Visit Day 5 in EDC, however same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' answered with 'data change form was completed' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:31:20
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 18Dec2020 is reported under Illness Visit Day 5 in EDC, however same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:02:48
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:41:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:42:31
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:30:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
Query 'Per GCL Lab Recon: Saliva: Sample dated 18Dec2020 is reported under Illness Visit Day 5 in EDC, however same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 11:02:41
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 18Dec2020 is reported under Illness Visit Day 5 in EDC, however same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:01:11
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:41:14
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:42:31
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:42:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:48:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:42:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:48:26
User entered '17 Dec 2020'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:30:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 25Dec2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:11:56
Query 'Per GCL Lab Recon: Saliva: Sample dated 25Dec2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' answered with 'data change form was completed' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:33:27
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 25Dec2020 is reported under Illness Visit Day 9 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:02:08
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

US3712271

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:30:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User closed query 'Please confirm as it seems a day 9 saliva was collected on 25Dec2020, which is out of window. If confirmed, please update and submit a DCF within PPD labs. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 19:18:42
Query 'Please confirm as it seems a day 9 saliva was collected on 25Dec2020, which is out of window. If confirmed, please update and submit a DCF within PPD labs. ' answered with 'updated date of collection and checking PPD labs ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:45:00
DataPoint Un-verified.	(b) (4), (b) (6)	12 Feb 2021 14:55:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:55:04
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:43:22
User opened query 'Please confirm as it seems a day 9 saliva was collected on 25Dec2020, which is out of window. If confirmed, please update and submit a DCF within PPD labs. ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 22:43:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50



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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:30:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered '25 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:34:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:26:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking 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)	18 Feb 2021 06:09:11
DataPoint Un-verified.	(b) (4), (b) (6)	12 Feb 2021 14:55:04
User entered '26 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:55:04
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:43:24
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:55:04
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 14:55:04
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50



**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:10:50

**US3712271**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:50:24
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:20:42
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:10:50

US3712271

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:13:57
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25DEC2020 and 29DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:41:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25DEC2020 and 29DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'subject was in hospital and unable to bring saliva swabs therefore only one done should be the 18DEC2020' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:37:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25DEC2020 and 29DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 05:55:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 15:07:54

US3712271

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:13:57
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:01:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:49:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:42:57
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:07:54

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:13:57
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:45:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Dec 2020 15:07:54

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:13:57
User entered 'SICKD1'	System	15 Dec 2020 15:07:54

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:09:23



**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '13:45'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User entered '14 Dec 2020 13:45'	System	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '162.4' cm	(b) (4), (b) (6)	15 Dec 2020 15:09:23
DataPoint set to visible.	System	15 Dec 2020 15:07:54

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '109.6' kg	(b) (4), (b) (6)	15 Dec 2020 15:09:23
DataPoint set to visible.	System	15 Dec 2020 15:07:54

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '37.5' C	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '92'	(b) (4), (b) (6)	15 Dec 2020 15:09:23



**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User entered 'bpm'	System	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '16'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

US3712271

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User entered 'breaths/min'	System	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '128'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User entered 'mmHg'	System	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:42
User entered '78'	(b) (4), (b) (6)	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15
User entered 'mmHg'	System	15 Dec 2020 15:09:23

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15



**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:15

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 15:09:39

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:48:57
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:09:39

US3712271

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:30:02

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 15:09:57

**US3712271**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:41
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:09:57

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:56
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:11:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:00:31

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:56
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 25DEC2020 for Day 7 and 29DEC2020 for Day 14 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 07:27:57
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 25DEC2020 for Day 7 and 29DEC2020 for Day 14 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'Subject was unable to bring in saliva samples due to being hospitalized ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 17:40:33
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Sample dated 25DEC2020 for Day 7 and 29DEC2020 for Day 14 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 06:26:53

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:11:43
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 21:00:31



**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:56
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:11:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 21:00:31

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:56
User entered 'SICKD28'	System	22 Jan 2021 21:00:31

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '10:56'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User entered '20 Jan 2021 10:56'	System	22 Jan 2021 21:01:55

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '162.4' cm	(b) (4), (b) (6)	22 Jan 2021 21:01:55
DataPoint set to visible.	System	22 Jan 2021 21:00:31

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '109.6' kg	(b) (4), (b) (6)	22 Jan 2021 21:01:55
DataPoint set to visible.	System	22 Jan 2021 21:00:31



**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '37.0' C	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '91'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User entered 'bpm'	System	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '16'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User entered 'breaths/min'	System	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '139'	(b) (4), (b) (6)	22 Jan 2021 21:01:55



**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User entered 'mmHg'	System	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:41
User entered '98'	(b) (4), (b) (6)	22 Jan 2021 21:01:55

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22
User entered 'mmHg'	System	22 Jan 2021 21:01:55

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:22

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:02:01

**US3712271**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:48
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 21:02:01

US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:30:02

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:11:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:02:14



US3712271

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:30:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User closed query 'Please confirm this date, as this is Out of Window by 2 days. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:45:01
Query 'Please confirm this date, as this is Out of Window by 2 days. ' answered with 'confirmed ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:38:27
User opened query 'Please confirm this date, as this is Out of Window by 2 days. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:11:33
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:11:06
User entered '20 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 21:02:14

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:47:48

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:47:48

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Mar 2021 20:47:48

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'UNBLND_DECIDE'	System	22 Mar 2021 20:47:48

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56



**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:30:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:30:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'I'	System	22 Mar 2021 20:48:56

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '1'	System	22 Mar 2021 20:48:56



US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered empty.	System	22 Mar 2021 20:49:51
DataPoint set to visible.	System	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered empty.	System	22 Mar 2021 20:49:51
DataPoint set to visible.	System	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51



US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '08:59'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '24 Feb 2021 08:59'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '37.0' C	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '89'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'bpm'	System	22 Mar 2021 20:49:51



US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'breaths/min'	System	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '129'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'mmHg'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '84'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'mmHg'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Mar 2021 20:49:51



**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:30:02**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered empty.	System	22 Mar 2021 20:49:51
DataPoint set to visible.	System	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '10:14'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '24 Feb 2021 10:14'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '37.1' C	(b) (4), (b) (6)	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Mar 2021 20:49:51



**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '89'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'bpm'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'breaths/min'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '128'	(b) (4), (b) (6)	22 Mar 2021 20:49:51

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'mmHg'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '85'	(b) (4), (b) (6)	22 Mar 2021 20:49:51



**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'mmHg'	System	22 Mar 2021 20:49:51

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 20:49:55

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:49:55

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:50:04

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:50:04

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

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)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 20:50:04

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'mRNA-1273'	System	22 Mar 2021 20:50:04
DataPoint set to visible.	System	22 Mar 2021 20:48:56

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:50:04



US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '09:44'	(b) (4), (b) (6)	22 Mar 2021 20:50:04

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '24 Feb 2021 09:44'	System	22 Mar 2021 20:50:04

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Mar 2021 20:50:04

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'ONCE'	System	22 Mar 2021 20:50:04

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 20:50:04

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:48:26

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:48:26

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '08:43'	(b) (4), (b) (6)	22 Mar 2021 20:48:26



**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '24 Feb 2021 08:43'	System	22 Mar 2021 20:48:26

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:30:02**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:48:34

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '24 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 20:48:34

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:30:02**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered '08:45'	(b) (4), (b) (6)	22 Mar 2021 20:48:34

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:30:02**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '24 Feb 2021 08:45'	System	22 Mar 2021 20:48:34

US3712271

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 20:53:06

**US3712271**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:33:53
User entered '1'	System	22 Mar 2021 20:53:06

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:44:56



**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:44:56

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:44:56

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:44:56

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:44:58

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User entered 'I'	System	30 Mar 2021 18:44:58

**US3712271**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:46
User entered '1'	System	30 Mar 2021 18:44:58
DataPoint set to visible.	System	30 Mar 2021 18:44:58

**US3712271**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:20:53

**US3712271**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:20:53



US3712271

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:20:53

**US3712271**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:30:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'OLD29'	System	06 Apr 2021 14:20:53

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '09:29'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered '25 Mar 2021 09:29'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '37.4' C	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37



**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '87'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'bpm'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'breaths/min'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '118'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'mmHg'	System	06 Apr 2021 14:21:37



US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '86'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'mmHg'	System	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '10:55'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered '25 Mar 2021 10:55'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37



**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '86'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'bpm'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'breaths/min'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '114'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'mmHg'	System	06 Apr 2021 14:21:37



US3712271

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '80'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:37

**US3712271**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'mmHg'	System	06 Apr 2021 14:21:37

US3712271

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:43

**US3712271**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:30:02**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:43

**US3712271**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

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)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

**US3712271**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'mRNA-1273'	System	06 Apr 2021 14:21:57
DataPoint set to visible.	System	30 Mar 2021 18:44:58



US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered '10:25'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

**US3712271**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:30:02**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered '25 Mar 2021 10:25'	System	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'ONCE'	System	06 Apr 2021 14:21:57

US3712271

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'INTRAMUSCULAR'	System	06 Apr 2021 14:21:57

**US3712271**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:00

**US3712271**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:05:36
User entered 'I'	System	06 Apr 2021 14:22:00



**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:50

**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:09
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:50

**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:50

**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:30:02**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:50

**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:22:52

**US3712271**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:30:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 14:22:52

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:30:02**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:37:55
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:14:14

US3712271

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:31:42
Un-reviewed for Safety.		11 Feb 2021 14:31:38
Reviewed for Safety.		10 Feb 2021 15:36:52
Un-reviewed for Safety.		10 Feb 2021 15:36:49
Reviewed for Safety.		10 Feb 2021 15:36:26
Un-reviewed for Safety.		10 Feb 2021 15:36:22
DataPoint Verified.		27 Jan 2021 16:44:28
Reviewed for Safety.		14 Jan 2021 14:51:09
User entered 'USA-US068-2021-mRNA-1273-P301000004'	System	14 Jan 2021 14:50:51
User entered 'New'	(b) (4), (b) (6)	14 Jan 2021 14:50:51



US3712271

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:35:18
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was covid-19 positive' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:50:59
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:31:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Bilateral pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 20:29:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 20:29:04
Data point term sent to Coder	System	13 Jan 2021 20:28:08
Coding entries removed.	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User entered 'bilateral pneumonia' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 20:26:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 20:26:05
Data point term sent to Coder	System	13 Jan 2021 20:25:04
User entered 'COVID-19'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:22:16
User closed query 'Please confirm, as this was established after Covid19 diagnosis. Please have PI / Sub-I assess and update as needed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:10:28
Query 'Please confirm, as this was established after Covid19 diagnosis. Please have PI / Sub-I assess and update as needed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:35:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:35:23
User opened query 'Please confirm, as this was established after Covid19 diagnosis. Please have PI / Sub-I assess and update as needed.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:57:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 20:22:19
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:48:30
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:48:30
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: Please provide the onset date for the event, bilateral pneumonia.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:07
Query 'PV Query: Please provide the onset date for the event, bilateral pneumonia.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 19:47:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 19:47:52
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:47:52
User opened query 'PV Query: Please provide the onset date for the event, bilateral pneumonia.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:45:20
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	10 Feb 2021 20:22:22
	(b) (4), (b) (6)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:49:26
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:49:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:49:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:48:30
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:17:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 18:13:43
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 18:13:43
User closed query 'PV Query: Please provide the event end date for bilateral pneumonia (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 15:36:32
Query 'PV Query: Please provide the event end date for bilateral pneumonia (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:50:29
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:48:30
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:48:30
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:48:30
User opened query 'PV Query: Please provide the event end date for bilateral pneumonia (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:58:03
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: Please provide the event end date for bilateral pneumonia and COVID-19 (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date for bilateral pneumonia and COVID-19 (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:48:17
User opened query 'PV Query: Please provide the event end date for bilateral pneumonia and COVID-19 (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:46:14
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Jan 2021 20:27:48
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Jan 2021 20:24:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'REQUERY: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:41:19
Query 'REQUERY: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'have been emailed ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:41:08
User opened query 'REQUERY: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 12:44:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 12:44:21
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:55:14
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
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)	20 Jan 2021 09:17:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'entered what is known.' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 20:31:45
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	13 Jan 2021 20:27:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 15:42:58
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)	10 Feb 2021 15:36:35
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 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:50:42
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:49:46
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:49:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:00:53
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:43:02
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 15:36:38
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:50:47
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:49:46
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:49:46
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:59:45
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:13
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:12
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:48:46
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'waiting for medical records' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:48:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:57:56
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:45:34
Query 'PV Query: Please provide the onset date for the event, bilateral pneumonia.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:45:08
User opened query 'PV Query: Please provide the onset date for the event, bilateral pneumonia.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:45:03
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:31:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

US3712271

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.	System	13 Jan 2021 20:24:19
	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.	System	13 Jan 2021 20:24:19
	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the events, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:15
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the events, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:49:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:49:05
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the events, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:47:03
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

None

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	11 Feb 2021 15:47:59
User closed query 'Please confirm, as the subject was hospitalized.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:47:56
Query 'Please confirm, as the subject was hospitalized.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:13:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 18:13:43
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:13:43
User opened query 'Please confirm, as the subject was hospitalized.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:06:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Jan 2021 20:27:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Jan 2021 20:24:19
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 11:39:49
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:39:14
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:46:04
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:48:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 18:13:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:13:43
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:17
Query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:49:25
User opened query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:47:34
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:24:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 15:48:08
User closed query 'PV Query: Please provide the final event outcome for bilateral pneumonia when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:21:40
Query 'PV Query: Please provide the final event outcome for bilateral pneumonia when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:14:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 18:13:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:13:43
User opened query 'PV Query: Please provide the final event outcome for bilateral pneumonia when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:59:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User closed query 'PV Query: Please provide the final event outcome for bilateral pneumonia and COVID-19, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:21
Query 'PV Query: Please provide the final event outcome for bilateral pneumonia and COVID-19, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'confirmed. waiting on medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:49:43

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome for bilateral pneumonia and COVID-19, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:45:50
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:27:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:27:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:27:48
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Narrative indicates that subject had "OXYGEN." 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). Query 'Per DM CLR: Narrative indicates that subject had "OXYGEN." 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 "'home oxygen" in ccmads' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:51:57
User opened query 'Per DM CLR: Narrative indicates that subject had "OXYGEN." 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). DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 12:34:23
User closed query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 03:44:50
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 15:49:07
User closed query 'PV Query: Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:22:54
User closed query 'PV Query: Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:22:43
User closed query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:22:12
Query 'PV Query: Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:15:36
Query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:15:29

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 18:15:23
	(b) (4), (b) (6)	10 Feb 2021 18:14:59
User entered 'Subject tested positive for COVID on 14DEC2020. Subject began to have increased shortness of breath with pulse oximeter showing in the 80's. Subject went to Fort Sanders Regional Medical Center on 21DEC2020. Subject had oxygen saturation of 90% with ambulation. She had a chest x-ray that confirmed COVID pneumonia with "ground glass opacities", greatest in the left lobe. Subject also had CT PE study that was negative for pulmonary embolism, but again showed the COVID pneumonia. Troponin resulted at <0.010, UA showed bacteriuria, and second chest x ray showed worsening. Lab tests show transaminitis with ALT of 59 and AST of 49, Lactic acid of 3.4, Anion gap of 15. EKG showed sinus tachycardia with a rate of 109. COVID-19 test was positive. Influenza swab was negative, and D. Dimer was 0.95. Subject was discharged on 24DEC2020 on 2L O2 NC.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:14:59
User opened query 'PV Query: Please provide treatment given for the event bilateral pneumonia including medical intervention and/or surgical treatments.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:56:44
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:55:23
User opened query 'PV Query: Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:54:57

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:54:47
User opened query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:51:45
Query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:51:26
User opened query 'PV Query: PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:51:18
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
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)	26 Jan 2021 17:30:24
User closed query 'PV Query: Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:22
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 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:50:08

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query:Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' answered with 'waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:50:04
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:55:31
Query 'PV Query: Day 11 symptom log on 21 Dec 2020 has subject temperature marked as 102.4 degrees Celsius please update the degree to Fahrenheit' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:49:59
User opened query 'PV Query: Day 11 symptom log on 21 Dec 2020 has subject temperature marked as 102.4 degrees Celsius please update the degree to Fahrenheit' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:49:22
User opened query 'PV Query:Please provide reports of all the investigations (ie. laboratory, radiological, EKG, etc.) done during the event, bilateral pneumonia duration.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:49:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Jan 2021 20:30:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Jan 2021 20:30:40
User entered 'Subject went to the ER due to difficulty breathing. Subject stated that they are running test on 21DEC2020. A CAT scan was done and showed bilateral pneumonia stated by subject. When I spoke to the subject on 22DEC2020, subject stated that she was admitted to the hospital and that she was on 3 liters of oxygen. I will follow up with more information when I get medical records.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:30:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Jan 2021 20:24:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:24:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 20:24:19



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 20:24:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 20:31:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
Reviewed for Safety.		14 Jan 2021 14:51:50
User entered 'USA-US068-2021-mRNA-1273-P301000004'		14 Jan 2021 14:51:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:34:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 20:34:05
Data point term sent to Coder	System	13 Jan 2021 20:33:11
User entered 'covid-19'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Yes (Y)'		13 Jan 2021 20:32:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'As per prior PVG query, symptoms began on 11Dec2020. If confirmed as reported on the symptom log, please update or clarify otherwise. As a reminder, please save after updating.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:51:14
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:51:13
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:05:20
Query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:07:27
Query 'As per prior PVG query, symptoms began on 11Dec2020. If confirmed as reported on the symptom log, please update or clarify otherwise. As a reminder, please save after updating.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:07:21
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:07:12
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:07:12
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:53:01
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User opened query 'As per prior PVG query, symptoms began on 11Dec2020. If confirmed as reported on the symptom log, please update or clarify otherwise. As a reminder, please save after updating.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:31:22



US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:30:34
Query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:43:32
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:50:58
User entered '14 Dec 2020'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:43:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Please confirm this end date as symptoms still persisted past this date. Please review the symptom log, as well as hospital records upon receipt. ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:53:19
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:53:17
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 18 Dec 2020; however, symptoms were still reported on 22 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:05:29
Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 18 Dec 2020; however, symptoms were still reported on 22 Dec 2020.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:09:24
Query 'Please confirm this end date as symptoms still persisted past this date. Please review the symptom log, as well as hospital records upon receipt. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:09:19
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:09:01
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:09:01
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 18 Dec 2020; however, symptoms were still reported on 22 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User opened query 'Please confirm this end date as symptoms still persisted past this date. Please review the symptom log, as well as hospital records upon receipt. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:04:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Jan 2021 16:51:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Jan 2021 16:51:04
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Jan 2021 19:43:26
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:43:26
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 20:32:45



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Please have PI / Sub-I review this severity ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:53:32
Query 'Please have PI / Sub-I review this severity ' answered with 'confirmed ' (Site from CRA).		09 Feb 2021 17:09:38
DataPoint Verified.		27 Jan 2021 16:44:28
User opened query 'Please have PI / Sub-I review this severity ' (Site from CRA).		27 Jan 2021 16:05:43
User entered 'Grade 1/Mild (Grade 1/Mild)'		13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'No (N)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	27 Jan 2021 16:44:28
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 15:53:42
User closed query 'Please confirm, as subject received both doses of vaccine or placebo, so should this be revised to "not applicable" if so, please update.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:53:40
Query 'Please confirm, as subject received both doses of vaccine or placebo, so should this be revised to "not applicable" if so, please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:09:52
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 17:09:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:09:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User opened query 'Please confirm, as subject received both doses of vaccine or placebo, so should this be revised to "not applicable" if so, please update.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:06:41
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:18:44
DataPoint Un-verified.		22 Mar 2021 19:07:15
User entered '0' reason for change: Data Entry Error		22 Mar 2021 19:07:15
DataPoint Verified.		27 Jan 2021 16:44:28
User entered '1'		13 Jan 2021 20:32:45



US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:18:49
User closed query 'Please confirm as it seems medications were administered during the hospitalization to treat Covid-19 as well as bilateral pneumonia.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:18:47
Query 'Please confirm as it seems medications were administered during the hospitalization to treat Covid-19 as well as bilateral pneumonia.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 19:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 19:07:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:07:15
User opened query 'Please confirm as it seems medications were administered during the hospitalization to treat Covid-19 as well as bilateral pneumonia.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:16:48
User closed query 'PV Query: Please provide treatment given for the event, COVID-19 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)	10 Feb 2021 16:05:38
Query 'PV Query: Please provide treatment given for the event, COVID-19 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 'no medication was taken ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:11:43
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event, COVID-19 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). User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 17:51:41
	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered '0'	(b) (4), (b) (6)	13 Jan 2021 20:32:45

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	26 Jan 2021 16:51:04
Data Entry Error		
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:32:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:32:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	13 Jan 2021 20:32:53
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:32:45
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:44:28
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

US3712271

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'PV Query: Day 11 symptom log on 21 Dec 2020 has subject temperature marked as 102.4 degrees Celsius please update the degree to Fahrenheit' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:05:43
Query 'PV Query: Day 11 symptom log on 21 Dec 2020 has subject temperature marked as 102.4 degrees Celsius please update the degree to Fahrenheit' answered with 'updating' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:15:08
Query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:08:54
User opened query 'PV Query: Day 11 symptom log on 21 Dec 2020 has subject temperature marked as 102.4 degrees Celsius please update the degree to Fahrenheit' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:53:44
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:44:28
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.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:52:32
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 11 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:50:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:44:17
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 20:32:45

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 20:32:45



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminitis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:18:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 14:18:57
Data point term sent to Coder	System	26 Feb 2021 14:17:25
User entered 'Transaminitis'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

US3712271

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:48:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 12:56:10
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 12:56:03
	(b) (4), (b) (6)	28 Feb 2021 22:00:36
	(b) (4), (b) (6)	26 Feb 2021 14:16:27

US3712271

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:16:27

US3712271

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:36:53
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE is still ongoing' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:18:45
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:59:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:18:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 19:08:13
User entered '0' reason for change: Data Entry Error		14 Apr 2021 19:08:13
DataPoint Verified.		14 Apr 2021 18:35:15
User entered '1'		26 Feb 2021 14:16:27

US3712271

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:18:00
User closed query 'Con med was noted, please advise and update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:17:57
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
Query 'Con med was noted, please advise and update or clarify otherwise.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 19:08:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:08:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User opened query 'Con med was noted, please advise and update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:23:37
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:16:27



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 14:16:27

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41

US3712271

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Asymptomatic bacteriuria, LLT: Asymptomatic bacteriuria - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:20:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:20:04
Data point term sent to Coder	System	26 Feb 2021 14:18:28
User entered 'asymptomatic bacteriuria'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:17:30



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User entered empty.	System	26 Feb 2021 14:17:30

US3712271

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:37:06
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:20:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:20:11
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:00:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

US3712271

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 19:23:05
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Apr 2021 19:23:05
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 19:20:11
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:20:11
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User entered empty.	System	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

US3712271

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:40:57
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'CEFTRIAXONE' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:52:31
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:00:40
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:17:30



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:23:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User entered '0'	System	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41
User entered 'I'	System	26 Feb 2021 14:17:30

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:41

US3712271

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:21:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:21:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 21:37:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Mar 2021 21:37:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 20:50:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 20:50:59
Data point term sent to Coder	System	26 Feb 2021 14:21:32
User entered 'acute respiratory failure with hypoxia'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '23 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:20:48

US3712271

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:18:48
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:10:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:09:43
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:00:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

US3712271

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Mar 2021 19:10:16
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Mar 2021 19:10:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Mar 2021 19:09:43
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:09:43
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:20:48

US3712271

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:02

Severity

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	01 May 2021 22:15:09
	(b) (4)	
User closed query 'Per MM: Please review and confirm the severity and seriousness. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 01:05:20
Query 'Per MM: Please review and confirm the severity and seriousness. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:49:09
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 15:48:07
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 15:48:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 15:48:07
User opened query 'Per MM: Please review and confirm the severity and seriousness. ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 13:55:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

US3712271

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:37:54
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'HOME OXYGEN, LEVALBUTEROL, ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:18:42
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:01:07
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:10:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:20:48

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:20:48



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:24:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:24:01
Data point term sent to Coder	System	26 Feb 2021 14:22:34
User entered 'sepsis'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User entered empty.	System	26 Feb 2021 14:22:19



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Mar 2021 12:52:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Mar 2021 12:52:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 14:22:19
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User entered empty.	System	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

US3712271

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:41:10
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'CEFTRIAXONE, ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:26:32
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:02:05
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 12:52:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User entered '0'	System	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49
User entered 'I'	System	26 Feb 2021 14:22:19

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:16:49

US3712271

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review this AE and please update to specify whether Left Lower Lobe Mass is Benign or Malignant. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:09:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 07:53:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 07:53:28
Data point term sent to Coder	System	22 Mar 2021 19:14:09
User closed query 'CDM Coding: Please clarify this clinical event (LEFT LOWER LOBE MASS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung mass, Hepatic mass etc)' (Site from System).	System	22 Mar 2021 19:13:43
Query 'CDM Coding: Please clarify this clinical event (LEFT LOWER LOBE MASS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung mass, Hepatic mass etc)' ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 19:13:43
User entered 'BENIGN LEFT LOWER lung LOBE MASS' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:13:29
Data point term sent to Coder	System	22 Mar 2021 19:13:08
Query 'Per DM CLR: Please review this AE and please update to specify whether Left Lower Lobe Mass is Benign or Malignant. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:13:05
User entered 'benign LEFT LOWER LOBE MASS' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:12:50

US3712271

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: Please clarify this clinical event (LEFT LOWER LOBE MASS) with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung mass, Hepatic mass etc)' (Site from System).	Coder Import (b) (4) (b) (4)	18 Mar 2021 17:02:50
User opened query 'Per DM CLR: Please review this AE and please update to specify whether Left Lower Lobe Mass is Benign or Malignant. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:02:20
Data point term sent to Coder	System	26 Feb 2021 19:55:36
User entered 'LEFT LOWER LOBE mass' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:55:15
Data point term sent to Coder	System	26 Feb 2021 14:26:37
User entered 'left lower lobe in buttocks'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '24 Nov 2020'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	14 Apr 2021 18:35:15
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:26:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:03:43
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:03:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:26:25



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:26:25



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:26:25

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 14:26:25

US3712271

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Diverticulum duodenal - version MedDRA\\23.0.	Coder Import (b) (4)	28 Feb 2021 15:45:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Feb 2021 15:45:25
Data point term sent to Coder	System	26 Feb 2021 14:28:39
User entered 'diverticulum of duodenum'	(b) (4), (b) (6)	26 Feb 2021 14:27:41



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '24 Nov 2020'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:27:41

US3712271

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:41:22
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'still ongoing ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:27:46
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:03:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 20:27:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:27:41

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:27:41



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:27:41

US3712271

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:30:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Lung opacity, LLT: Lung opacity - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 12:46:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 12:46:41
Data point term sent to Coder	System	26 Feb 2021 14:29:39
User entered 'left lower lobe patchy ground glass opacities'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

US3712271

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:30:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:29:23



US3712271

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:41:29
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'still ongoing ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:28:14
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 20:29:11
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

US3712271

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:30:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:14:28
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 20:29:26
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:29:11
User entered '1'	(b) (4), (b) (6)	17 Mar 2021 14:04:22
	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23



**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:35:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:29:23

**US3712271**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 14:29:23

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:30:02**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:07
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:53

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 11:53:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 11:53:31
Data point term sent to Coder	System	26 Oct 2020 11:52:59
User entered 'atenolol'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'hypertension'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:44:23
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:50:18
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '50'	(b) (4), (b) (6)	26 Oct 2020 11:52:41



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2000'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 11:52:41



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:52:41

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:52:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 11:52:41

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:55:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:55:27
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 11:54:01
User entered 'amlodipine'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'hypertension'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '5'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:53:13



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:53:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 11:53:13



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Con Med OZEMPIC was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:18:42
Query 'Per DM CLR: Con Med OZEMPIC was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Did not worsen ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:19:39
User opened query 'Per DM CLR: Con Med OZEMPIC was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:00:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 20:46:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 20:46:18
Data point term sent to Coder	System	22 Jan 2021 20:44:38
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 20:44:28

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:56:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:56:25
Data point term sent to Coder	System	26 Oct 2020 11:55:02
User entered 'ozempic'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0.5'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:01:25
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:44:07
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:43:57
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:51:59
User entered 'mL (mL)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every week (QS)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:54:20

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:01:28
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:44:33
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:44:28
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:13:24
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '01 Sep 2020'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:54:20



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:54:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	26 Oct 2020 11:54:20

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 20:46:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 20:46:19
Data point term sent to Coder	System	22 Jan 2021 20:45:39
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 20:44:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 11:58:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 11:58:24
Data point term sent to Coder	System	26 Oct 2020 11:58:03
User entered 'lantus'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '25'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'units'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:57:33

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:01:51
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:44:53
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:44:48
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:13:48
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 11:57:33

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 11:57:33

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 20:46:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 20:46:20
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 20:45:41
Coding entries removed.	(b) (4), (b) (6)	22 Jan 2021 20:45:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:56:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:56:29
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 12:03:05
User entered 'humalog'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	26 Oct 2020 12:03:04



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '15'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'units'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:04

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:02:03
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:45:09
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:45:04
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:14:16
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Oct 2020 12:03:04



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:03:04

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:03:04

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE HYDROCHLORIDE, PRODUCTSYNONYM: REQUIP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:05:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:05:26
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 12:04:06
User entered 'requip'	(b) (4), (b) (6)	26 Oct 2020 12:03:40



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'restless leg syndrome'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2017'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:03:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:03:40



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:03:40

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
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 SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:37:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:37:50
Data point term sent to Coder	System	26 Oct 2020 12:05:06
User entered 'protonix'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'acid reflux'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '40'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2010'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:04:27



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:04:27

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:04:27

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:06:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:06:32
Data point term sent to Coder	System	26 Oct 2020 12:05:06
User entered 'effexor'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'anxiety'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '150'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:51

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2004'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:04:51

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:04:51

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:09:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:09:27
Data point term sent to Coder	System	26 Oct 2020 12:08:07
User entered 'vitamin b'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:43:44
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:48:59
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:59:00
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:05:12
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'supplement'	(b) (4), (b) (6)	26 Oct 2020 12:07:16



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:10:20
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 17:44:09
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:44:04
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:10:50
User entered '2.4'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:44:04
User entered 'ug (ug)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Oct 2020 12:07:16



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:07:16

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:07:16

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:10:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:10:30
Data point term sent to Coder	System	26 Oct 2020 12:09:08
User entered 'vitamin d'	(b) (4), (b) (6)	26 Oct 2020 12:08:40



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 21:43:48
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:49:04
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:59:15
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:05:24
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'supplement'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '15'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'ug (ug)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:08:40

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2008'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:08:40

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:08:40



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:08:40

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
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.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:10:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:10:28
Data point term sent to Coder	System	26 Oct 2020 12:09:07
User entered 'metformin'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'diabetes'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Please confirm dosage, medical records note 500 mg 2 tabs BID. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:02:45
Query 'Please confirm dosage, medical records note 500 mg 2 tabs BID. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:00:28
User entered '500' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:00:22
User opened query 'Please confirm dosage, medical records note 500 mg 2 tabs BID. ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 21:09:44
User entered '2000'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:09:03

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:00:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2019'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 12:09:03



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 19:00:22
User entered '1'	System	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:09:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:09:03

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Con Med ZETIA was added/changed on 19 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition HYPERCHOLESTEROLEMIA requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:14
Query 'Per DM CLR: Con Med ZETIA was added/changed on 19 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition HYPERCHOLESTEROLEMIA requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'hypercholesterolemia has not worsened' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:23:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 19:23:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Mar 2021 19:23:17 22 Mar 2021 19:22:57
User opened query 'Per DM CLR: Con Med ZETIA was added/changed on 19 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition HYPERCHOLESTEROLEMIA requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:03:40
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:04:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:04:13
Data point term sent to Coder	System	21 Jan 2021 18:57:21
User entered 'ZETIA'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:50:46
DataPoint Un-verified.		22 Mar 2021 19:22:57
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Data Entry Error		22 Mar 2021 19:22:57
DataPoint Verified.		04 Mar 2021 16:59:00
User entered 'HYPERLIPIDEMIA'		21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '10'	(b) (4), (b) (6)	21 Jan 2021 18:56:46



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '19 Nov 2020'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	21 Jan 2021 18:56:46



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 18:56:46

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 18:56:46

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:29:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:29:50
Data point term sent to Coder	System	13 Apr 2021 19:24:46
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:24:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 00:36:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 00:36:43
Data point term sent to Coder	System	10 Feb 2021 18:32:32
User entered 'ascorbic acid'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:53:01
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:24:03
User entered 'treatment of COVID-19 while HOSPITALIZATION' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:24:03
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 10:19:04
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'AE updated ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:24:54
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:22:20
User entered 'covid-19 hospitalization'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '500'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:32:29



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User entered '1'	System	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User entered '1'	System	10 Feb 2021 18:32:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:15
User entered '804 (804)'	System	10 Feb 2021 18:32:29



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
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.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:34:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:34:50
Data point term sent to Coder	System	10 Feb 2021 18:34:33
User entered 'ezetimibe'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'hyperlipidemia'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '10'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:33:41



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '01 Oct 2020'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '01 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User entered '1'	System	10 Feb 2021 18:33:41



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User entered '1'	System	10 Feb 2021 18:33:41

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:19
User entered '804 (804)'	System	10 Feb 2021 18:33:41

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC GLUCONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 08:05:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:05:42
Data point term sent to Coder	System	13 Apr 2021 19:25:47
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:25:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 12:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 12:06:39
Data point term sent to Coder	System	10 Feb 2021 18:34:34
User entered 'zinc gluconate'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 18:53:51
DataPoint Un-verified.		3 Apr 2021 19:25:03
User entered 'Yes (Y)' reason for change: Data Entry Error		3 Apr 2021 19:25:03
DataPoint Verified.		4 Mar 2021 16:59:00
User entered 'No (N)'		0 Feb 2021 18:34:13

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	14 Apr 2021 18:54:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:25:03
User entered 'treatment of covid-19 while hospitalized/ prevention of covid' reason for change:	(b) (4), (b) (6)	13 Apr 2021 19:25:03
Data Entry Error		
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	25 Mar 2021 10:19:34
' (Site from DM).		
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	22 Mar 2021 19:31:46
' answered with 'AE has been updated' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	04 Mar 2021 12:31:59
' (Site from DM).		
User entered 'covid-19'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '50'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:13



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:22
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'still ongoing ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:25:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:26:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:13



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:34:13

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 18:34:13

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:35:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:35:50
Data point term sent to Coder	System	10 Feb 2021 18:35:35
User entered 'multivitamin'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'supplement'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 18:34:42



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:30:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:34:42



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:34:42

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:30:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:34:42

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 18:34:42

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:36:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:36:49
Data point term sent to Coder	System	10 Feb 2021 18:36:36
User entered 'aspirin'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'cardiac prophylaxis '	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '81'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:30:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:36:19



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2017'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:36:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 18:36:19



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 09:33:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:33:51
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Apr 2021 19:27:51 13 Apr 2021 19:27:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:49:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:49:51
Data point term sent to Coder User entered 'enoxaparin'	System (b) (4), (b) (6)	10 Feb 2021 18:48:51 10 Feb 2021 18:47:58

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:54:43
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:27:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:27:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:54:47
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:27:22
User entered 'Deep vein thrombosis prophylaxis while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:27:22
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	25 Mar 2021 10:19:51
' (Site from DM).		
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	22 Mar 2021 19:35:31
' answered with 'AE has been updated' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	04 Mar 2021 12:32:55
' (Site from DM).		
User entered 'covid-19'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '110'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every 12 hours'	(b) (4), (b) (6)	10 Feb 2021 18:47:58



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User entered empty.	System	10 Feb 2021 18:47:58



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User entered empty.	System	10 Feb 2021 18:47:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:09
User entered empty.	System	10 Feb 2021 18:47:58

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:47:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:47:09
Data point term sent to Coder	System	13 Apr 2021 19:28:54
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:28:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 18:50:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 18:50:50
Data point term sent to Coder	System	10 Feb 2021 18:49:52
User entered 'lactated ringers'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:54:59
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:28:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:00
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:36
User entered 'prevention of dehydration while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:28:36
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	25 Mar 2021 10:19:58
' (Site from DM).		
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	22 Mar 2021 19:39:09
' answered with 'AE updated' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	04 Mar 2021 12:33:17
' (Site from DM).		
User entered 'covid-19 inpatient'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '100'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mL (mL)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:49:08



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:49:08



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User entered '1'	System	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User entered '1'	System	10 Feb 2021 18:49:08

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:01
User entered '804 (804)'	System	10 Feb 2021 18:49:08

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
Data point term sent to Coder	System	13 Apr 2021 19:29:56
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:29:34
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 00:45:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 00:45:43
Data point term sent to Coder	System	10 Feb 2021 18:50:54
User entered 'dexamethasone'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:13
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:34
User entered 'treatment of pneumonia after hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:29:34
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	25 Mar 2021 10:20:04
' (Site from DM).		
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	22 Mar 2021 19:39:41
' answered with 'AE updated' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	04 Mar 2021 12:33:27
' (Site from DM).		
User entered 'inpatient covid-19'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '2'	(b) (4), (b) (6)	10 Feb 2021 18:50:03



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '3 tablets daily'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:50:03



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '30 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User entered empty.	System	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User entered empty.	System	10 Feb 2021 18:50:03

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:44:06
User entered empty.	System	10 Feb 2021 18:50:03

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:49:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:49:41
Data point term sent to Coder	System	13 Apr 2021 19:30:57
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 11:23:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 11:23:41
Data point term sent to Coder	System	26 Feb 2021 14:37:46
User entered 'home oxygen'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:21
DataPoint Un-verified.		13 Apr 2021 19:30:51
User entered 'Yes (Y)' reason for change: Data Entry Error		13 Apr 2021 19:30:51
DataPoint Verified.		04 Mar 2021 16:59:00
User entered 'No (N)'		26 Feb 2021 14:37:00



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:30:51
User entered 'treatment of ACUTE RESPIRATORY FAILURE due to covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:30:51
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '2'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'LPM'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:37:00



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 14:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Feb 2021 14:37:13
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Feb 2021 14:37:00
User entered '07 Jan 2021'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:30:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:30
User closed query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study and does not coincide with the treatment dates (22OCT2020 and 19NOV2020). Review response if this should be updated to "No" as appropriate. Otherwise, update Con Med eCRF or provide comment. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:52:17
Query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study and does not coincide with the treatment dates (22OCT2020 and 19NOV2020). Review response if this should be updated to "No" as appropriate. Otherwise, update Con Med eCRF or provide comment. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:40:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 19:40:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:40:06
User opened query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study and does not coincide with the treatment dates (22OCT2020 and 19NOV2020). Review response if this should be updated to "No" as appropriate. Otherwise, update Con Med eCRF or provide comment. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:00:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User entered empty.	System	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User entered empty.	System	26 Feb 2021 14:37:00

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:02
User entered empty.	System	26 Feb 2021 14:37:00



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 06:38:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:38:43
Data point term sent to Coder	System	13 Apr 2021 19:31:57
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:31:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 22:44:55
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 Feb 2021 22:44:55
Data point term sent to Coder	System	26 Feb 2021 14:38:47
User entered 'acetaminophen '	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:37
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:31:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:39
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:31:21
User entered 'prevention of pain while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:31:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '975'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:38:29



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:30:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:38:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User entered empty.	System	26 Feb 2021 14:38:29



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User entered empty.	System	26 Feb 2021 14:38:29

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:18
Data entry unlocked.	(b) (4), (b) (6)	02 May 2021 06:50:11
Data entry locked.	(b) (4), (b) (6)	02 May 2021 06:50:05
User entered empty.	System	26 Feb 2021 14:38:29

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL, PRODUCTSYNONYM: LEVALBUTEROL [LEVOSALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:04:46
Data point term sent to Coder	System	13 Apr 2021 19:33:02
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:32:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL, PRODUCTSYNONYM: LEVALBUTEROL [LEVOSALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:27:42
Data point term sent to Coder	System	26 Feb 2021 14:40:53
User entered 'levalbuterol'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:46
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:55
User entered 'Yes (Y)' reason for change: Data Entry Error		13 Apr 2021 19:32:55
DataPoint Verified.		04 Mar 2021 16:59:00
User entered 'No (N)'		26 Feb 2021 14:40:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:55:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:50
User entered 'treatment of pneumonia / respiratory failure due to covid-19 while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:32:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '90'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'ug (ug)'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:40:39



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:40:39



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User entered empty.	System	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User entered empty.	System	26 Feb 2021 14:40:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:23
User entered empty.	System	26 Feb 2021 14:40:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:43:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:43:00
Data point term sent to Coder	System	26 Feb 2021 14:41:54
User entered 'mirtazapine'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
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 MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:57
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 MH eCRF.' answered with 'added to medhx ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:59:53
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 MH eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:02:30
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'insomnia'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '15'	(b) (4), (b) (6)	26 Feb 2021 14:41:21



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:30:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:41:21



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:41:21

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 14:41:21

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 18:06:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 18:06:54
Data point term sent to Coder	System	26 Feb 2021 14:43:01
User entered 'tizanidine'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'restless leg'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '4'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:30:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:42:58



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:30:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:24
User closed query 'Per DM CLR: Please note that Con Med start date (UN UNK 2016) is prior to the start date of the corresponding MH (UN UNK 2017). Please review and reconcile the Con Med and MH start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:19:39
Query 'Per DM CLR: Please note that Con Med start date (UN UNK 2016) is prior to the start date of the corresponding MH (UN UNK 2017). Please review and reconcile the Con Med and MH start dates and correct as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 20:03:09
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 20:02:54
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 20:02:54
User opened query 'Per DM CLR: Please note that Con Med start date (UN UNK 2016) is prior to the start date of the corresponding MH (UN UNK 2017). Please review and reconcile the Con Med and MH start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:03:32
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'un UNK 2016'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 14:42:58

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 14:42:58



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:16:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 16:16:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:53:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:53:52
Data point term sent to Coder	System	13 Apr 2021 19:34:08
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:33:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 00:09:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 00:09:42
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00

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**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	26 Feb 2021 14:47:05
User entered 'sodium chloride 0.9%'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:35
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:33:41
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:39
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:33:41
User entered 'prevention of dehydration during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:33:41
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '1000'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mL (mL)'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:46:35

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 14:54:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 14:54:07
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 14:54:07
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 14:46:35
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:46:35



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:46:35



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User entered empty.	System	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User entered empty.	System	26 Feb 2021 14:46:35

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:50:43
User entered empty.	System	26 Feb 2021 14:46:35

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:58:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:58:41
Data point term sent to Coder	System	13 Apr 2021 19:35:13
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:35:04
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:50:58
Data point term sent to Coder	System	26 Feb 2021 14:53:19
User entered 'ceftriaxone'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:46
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:35:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:56:52
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:35:04
User entered 'treatment of pneumonia BACTERIURIA and sepsis while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:35:04
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '1000'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:53:19

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	26 Feb 2021 14:54:01
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	26 Feb 2021 14:54:01
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 14:54:01
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	26 Feb 2021 14:53:19
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User entered empty.	System	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User entered empty.	System	26 Feb 2021 14:53:19

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:46
User entered empty.	System	26 Feb 2021 14:53:19

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:01:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:01:54
Data point term sent to Coder	System	13 Apr 2021 19:36:14
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:35:42
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:14:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:14:43
Data point term sent to Coder	System	26 Feb 2021 14:57:22
User entered 'iohexol'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:04
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:35:48
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:35:42
User entered 'contrast used for imaging while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:35:42
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:04:06
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 14:56:32



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '100'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mL (mL)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:56:32



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User entered empty.	System	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User entered empty.	System	26 Feb 2021 14:56:32

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:42
User entered empty.	System	26 Feb 2021 14:56:32

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
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.	Coder Import (b) (4)	14 Apr 2021 09:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:37:47
Data point term sent to Coder	System	13 Apr 2021 19:37:15
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:36:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
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.	Coder Import (b) (4)	02 Mar 2021 07:44:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 07:44:21
Data point term sent to Coder	System	26 Feb 2021 15:01:28
User entered 'famotidine'	(b) (4), (b) (6)	26 Feb 2021 15:01:18



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:57:15
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:36:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:36:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:57:20
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:36:22
User entered 'prevention of Gastroesophageal reflux disease while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:36:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'inpatient hospital covid-19 treatment'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '20'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every 12 hours'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User entered empty.	System	26 Feb 2021 15:01:18

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User entered empty.	System	26 Feb 2021 15:01:18



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:59
User entered empty.	System	26 Feb 2021 15:01:18

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
Data point term sent to Coder	System	13 Apr 2021 19:37:15
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:36:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:22:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:22:58
Data point term sent to Coder	System	01 Mar 2021 12:36:52
User entered 'dexamethasone'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:57:31
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:36:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:36:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:57:33
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:36:58
User entered 'treatment of pneumonia due to covid-19 while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:36:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '4'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:09:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every 12 hours' reason for change:	(b) (4), (b) (6)	01 Mar 2021 13:09:17
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:36:31



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User entered empty.	System	01 Mar 2021 13:09:17
User entered '1'	System	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User entered empty.	System	01 Mar 2021 13:09:17
User entered '1'	System	01 Mar 2021 12:36:31

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:56
User entered empty.	System	01 Mar 2021 13:09:17
User entered '804 (804)'	System	01 Mar 2021 12:36:31

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:19:55
Data point term sent to Coder	System	13 Apr 2021 19:38:17
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:37:34
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:22:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:22:59
Data point term sent to Coder	System	01 Mar 2021 12:38:52
User entered 'dexamethasone'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:57:53
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:37:34
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:57:56
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:34
User entered 'treatment of pneumonia due to covid-19 while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:37:34
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '6'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:09:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every 12 hours' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:09:27
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:09:27
User entered '1'	System	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:09:27
User entered '1'	System	01 Mar 2021 12:38:37

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:09:27
User entered '804 (804)'	System	01 Mar 2021 12:38:37

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:56:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:56:05
Data point term sent to Coder	System	13 Apr 2021 19:38:17
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:37:57
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 12:42:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 12:42:47
Data point term sent to Coder	System	01 Mar 2021 12:41:54
User entered 'acetaminophen'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:58:14
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:37:57
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:58:16
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:37:57
User entered 'prevention of fever while hospitalized'	(b) (4), (b) (6)	13 Apr 2021 19:37:57
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:41:39



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '650'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:30:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:41:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:30:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'every 6 hours as needed'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:41:39



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 12:41:39

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 12:41:39

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:46
Data point term sent to Coder	System	13 Apr 2021 19:39:18
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:43
Data point term sent to Coder	System	01 Mar 2021 12:42:54
User entered 'insulin lispro'	(b) (4), (b) (6)	01 Mar 2021 12:42:53



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:58:45
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:58:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:39:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:09
User entered 'treatment of diabetes mellitus during hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:09
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:08:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '4'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'units'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User entered empty.	System	01 Mar 2021 12:42:53

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User entered empty.	System	01 Mar 2021 12:42:53



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:48:52
User entered empty.	System	01 Mar 2021 12:42:53

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:46
Data point term sent to Coder	System	13 Apr 2021 19:40:33
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:39:27
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:43
Data point term sent to Coder	System	01 Mar 2021 12:44:55
User entered 'insulin lispro'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:27
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:59:09
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:39:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:39:27
User entered 'treatment of diabetes mellitus during hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:27
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:08:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'l'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'unit'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'with meds 2 hours'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:09



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User entered empty.	System	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User entered empty.	System	01 Mar 2021 12:44:09

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:05
User entered empty.	System	01 Mar 2021 12:44:09

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:11:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:11:42
Data point term sent to Coder	System	13 Apr 2021 19:40:33
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:40:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:50:41
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
Data point term sent to Coder	System	01 Mar 2021 12:45:55
User entered 'remdesivir'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:59:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:59:25
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:01
User entered 'treatment of covid-19 while hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '200'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User entered '1'	System	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User entered '1'	System	01 Mar 2021 12:44:59

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:09
User entered '804 (804)'	System	01 Mar 2021 12:44:59

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:30:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:59:48
Data point term sent to Coder	System	13 Apr 2021 19:40:34
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:40:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:14:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:14:42
Data point term sent to Coder	System	01 Mar 2021 12:46:56
User entered 'insulin glargine'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:59:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:13:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:59:36
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:40:22
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:16
User entered 'treatment of diabetes mellitus during hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:10:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:46:28



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '30'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'units'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:46:28



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '24 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User entered '1'	System	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User entered '1'	System	01 Mar 2021 12:46:28

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:17
User entered '804 (804)'	System	01 Mar 2021 12:46:28

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:58:47
Data point term sent to Coder	System	13 Apr 2021 19:41:37
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:40:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:13:44
Data point term sent to Coder	System	01 Mar 2021 12:47:56
User entered 'insulin lispro'	(b) (4), (b) (6)	01 Mar 2021 12:47:26



US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:30:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:59:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:14:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:59:51
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 19:40:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:40:38
User entered 'treatment of diabetes mellitus during hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:40:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:10:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '15'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'units'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User entered empty.	System	01 Mar 2021 12:47:26

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User entered empty.	System	01 Mar 2021 12:47:26



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:22
User entered empty.	System	01 Mar 2021 12:47:26

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:30:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:34:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:34:44
Data point term sent to Coder	System	13 Apr 2021 19:43:38
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 19:43:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:37:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 13:37:49
Data point term sent to Coder	System	01 Mar 2021 12:48:58
User entered 'ergocalciferol'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

US3712271

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:30:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:00:05
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:43:22
User entered 'TREATMENT OF COVID-19 WHILE HOSPITALIZED' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:43:22
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'covid-19 inpatient treatment'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '50000'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'IU (IU)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered '21 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:59:00
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 12:48:20



**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User entered empty.	System	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User entered empty.	System	01 Mar 2021 12:48:20

**US3712271**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:30:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:27
User entered empty.	System	01 Mar 2021 12:48:20

US3712271

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:30:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:44:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:18:50
User closed query 'Please confirm, as during subject's hospitalization, Chest xray was performed and CT of chest. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:18:48
Query 'Please confirm, as during subject's hospitalization, Chest xray was performed and CT of chest. ' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 20:28:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 20:24:18
User opened query 'Please confirm, as during subject's hospitalization, Chest xray was performed and CT of chest. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:11:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 16:14:13

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:30:02**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:30

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'chest x-ray'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:30

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:30

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:30:02**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:30



**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:30:02**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:58

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'chest ct'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:58

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:58

**US3712271**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:30:02**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:00:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:27:58

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4)	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4) '	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
User entered '14/Jan/2021 14:54'	System	14 Jan 2021 14:54:13

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:30:02

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4)	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
User entered '26/Jan/2021 12:32'	System	26 Jan 2021 17:32:31

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:30:02

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:40:04
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 17:32:31



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4)	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '10/Feb/2021 10:41'	(b) (4) System	10 Feb 2021 15:41:19

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:30:02

**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)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 15:41:19
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 15:41:05

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4)	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '11/Feb/2021 09:33'	(b) (4) System	11 Feb 2021 14:33:28

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:30:02

**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)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:48:44
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 14:33:28

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47



US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4)	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered '23/Mar/2021 08:48'	(b) (4) System	23 Mar 2021 13:49:01

US3712271

Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:30:02

**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)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:49:01

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered		
'USA-US068-2021-MRNA-1273-P301000004'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51



**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Yes (Y)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

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**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

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**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'No (N)'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'William'	System	14 Jan 2021 14:50:51

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered 'Smith'	System	14 Jan 2021 14:50:51



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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:54
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:32:57
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 13:49:01
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered empty.	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:00
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:49:47

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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 13:49:01
User entered (b) (4) '	System	23 Mar 2021 13:49:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:33:02
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:47
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:49:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 14:54:05
User entered (b) (4) '	System	14 Jan 2021 14:50:51

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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:53:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 17:32:20
User entered 'US'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:30:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	14 Apr 2021 14:44:30
User entered '5'	System	23 Mar 2021 13:49:01
User entered '4'	System	11 Feb 2021 14:33:28
User entered '3'	System	10 Feb 2021 15:41:19
User entered '2'	System	26 Jan 2021 17:32:31
User entered '1'	System	14 Jan 2021 14:54:13

**US3712271**

**Folder: SAE USA-US068-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:30:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:38:03
User entered '14/Apr/2021 07:44'	System	14 Apr 2021 14:44:30

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Folder: SAE USA-US068-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:30:02

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:31:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:38:03
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 14:44:30