

US3922067 (Prod: Synexus Clinical Research US, Inc. - Dallas)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:22:24

All time stamps listed in this document are displayed in GMT

US3922067

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:33:36

Generated On: 10 Jun 2021 10:22:24

[Participant ID](#)

US3922067

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

US3922067

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3922067

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
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) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Date of Informed Consent (*dd MMM yyyy*) 01 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	HYPOTHYROIDISM
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 (2)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ATRIAL FIBRILLATION
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 (4)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	LEFT BREAST CANCER
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	21 JAN 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN DEC 1953
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 1953
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1953
Start Year (derived)	1953
Stop Month and Year (derived)	DEC 1953
Stop Year (derived)	1953

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	OSTEOARTHRITIS BILATERAL HANDS
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 (9)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	SLEEP APNEA
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 (10)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	LUMPECTOMY LEFT BREAST(CANCEROUS)
Start date (dd MMM yyyy)	21 JAN 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)	21 JAN 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 (13)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	BLADDER SUSPENSION
Start date (dd MMM yyyy)	05 SEP 2001
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)	05 SEP 2001
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2001
Start Year (derived)	2001
Stop Month and Year (derived)	SEP 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	12 MAR 1982
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)	12 MAR 1982
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1982
Start Year (derived)	1982
Stop Month and Year (derived)	MAR 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN JUN 1973
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 1973
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JUN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	RIGHT BREAST CYST REMOVAL BENIGN
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	07 JUN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	07 JUN 2018
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JUN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	RIGHT SHOULDER REPLACEMENT
Start date (dd MMM yyyy)	30 DEC 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 DEC 2011
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2011
Start Year (derived)	2011
Stop Month and Year (derived)	DEC 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	LEFT SHOULDER REPLACEMENT
Start date (dd MMM yyyy)	09 SEP 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	09 SEP 2011
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2011
Start Year (derived)	2011
Stop Month and Year (derived)	SEP 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN DEC 1953
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 1953
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1953
Start Year (derived)	1953
Stop Month and Year (derived)	DEC 1953
Stop Year (derived)	1953

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	LEFT SHOULDER PAIN
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	09 SEP 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	SEP 2011
Stop Year (derived)	2011

US3922067

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	RIGHT SHOULDER PAIN
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 DEC 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	DEC 2011
Stop Year (derived)	2011

US3922067

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	DIZZINESS
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)	_____

US3922067

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	CHRONIC RECURRENT UTI'S
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 (29)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	CHRONIC SHORTNESS OF BREATH
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 (30)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ALLERGY TO CIPROFLOXACIN
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 (32)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ALLERGY TO ERYTHROMYCIN
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ALLERGY TO NITROFURANTOIN
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 (34)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1950
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1950
Start Year (derived)	1950
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

Condition	ALLERGY TO SEPTRA
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 (36)

Data signed: (b) (4) 19 Apr 2021 13:13:17

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:47 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:47
Height (<i>xxx.x</i>)	68.0 in
Weight (<i>xxx.x</i>)	236.6 lb
BMI (<i>xxx.x</i>)	36.05013 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 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) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*) 1 SEP 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*) 12 MAR 1982

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

US3922067

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:33:40

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

US3922067

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189194

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 ☒

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Height	ND - Not Done
Weight	ND - Not Done

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:47
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 14:54
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3922067

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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.

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 14:05 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 14:05

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

US3922067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	11:54 (24 HR)
Collection date and time (derived)	1 SEP 2020 11:54

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:07	1 SEP 2020 13:07
Nasopharyngeal Swab 2	No		

US3922067

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 15:04

PC Open Date & Time

01 SEP 2020 14:25

PC Close Date & Time

01 SEP 2020 16:55

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	01 SEP 2020 23:15
PC Open Date & Time	01 SEP 2020 17:50
PC Close Date & Time	02 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 00:25

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 01:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 00:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 00:46

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

01 SEP 2020 15:04

PC Open Date & Time

01 SEP 2020 14:25

PC Close Date & Time

01 SEP 2020 16:55

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

01 SEP 2020 23:09

PC Open Date & Time

01 SEP 2020 17:50

PC Close Date & Time

02 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

02 SEP 2020 20:51

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

03 SEP 2020 21:35

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

05 SEP 2020 01:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

06 SEP 2020 00:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

06 SEP 2020 23:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

08 SEP 2020 00:47

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 15:05
PC Open Date & Time	01 SEP 2020 14:25
PC Close Date & Time	01 SEP 2020 16:55

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 23:09
PC Open Date & Time	01 SEP 2020 17:50
PC Close Date & Time	02 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

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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US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:51
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

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 ☒

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:36
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

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 ☒

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 01:47
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

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 ☒

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 00:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 23:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

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 ☒

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 00:47
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3922067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

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

THIS VISIT WAS NOT DONE
DUE TO SUBJECT WAS IN
HOSPITAL FOR CONFUSION.

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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 VISIT2

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3922067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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.

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

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

PER EPIP COMMENTS, BASED ON ONGOING UNRESOLVED ISSUES, SUB-I FELT IT WAS NOT IN SUBJECTS BEST INTEREST TO RECEIVE 2ND VACCINE DOSE.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3922067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3922067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:40

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:41

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:33:41

Generated On: 10 Jun 2021 10:22:24

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) _____

US3922067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:33:41

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3922067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:33:41

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	10:36 (24 HR)
Collection date and time (derived)	29 OCT 2020 10:36

US3922067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:41

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 16:44:23
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 09:35:09

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	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 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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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	29 NOV 2020 16:03:04
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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	03 DEC 2020 08:54:01
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

10 DEC 2020 10:47:21

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 10:08:12
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 DEC 2020 16:07:01
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

31 DEC 2020 00:02:14

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 02:42:21

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 11:57:45

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

21 JAN 2021 11:54:35

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

30 JAN 2021 13:31:05

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

04 FEB 2021 00:56:21

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

11 FEB 2021 00:01:30

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

18 FEB 2021 00:03:18

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

25 FEB 2021 09:02:56

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

04 MAR 2021 00:01:27

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

11 MAR 2021 11:48:52

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 09:14:09

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:00:21

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 20:32:03

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 00:01:48

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 13:57:54

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 11:43:49

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 10:05:56

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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°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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 271

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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="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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 <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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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="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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

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

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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="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"/>

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3922067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:22:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:16:43

US3922067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 22:38:45

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 22:38:45

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 21 Apr 2021 13:04:36

Generated On: 10 Jun 2021 10:22:24

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

Visit date (dd MMM yyyy)	13 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Apr 2021 13:04:36

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 10:20
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Apr 2021 13:04:36

Generated On: 10 Jun 2021 10:22:24

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.

US3922067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Apr 2021 13:04:36

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	13 APR 2021
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Collection time (00:00-23:59)	10:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	13 APR 2021 10:30
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US3922067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 21 Apr 2021 13:04:35

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 12:04:53

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 12:04:53

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

Date of Contact 28 SEP 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☒

Clinical Visit - Unscheduled ☐

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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	07 SEP 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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

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US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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"/>

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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"/>

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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	08 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (3)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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	09 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (4)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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	10 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (6)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input 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) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (12)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (14)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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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Form: Symptom Log (15)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 type="checkbox"/>
Day 21	<input checked="" 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 28 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" 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 28 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	97.3 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" 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 28 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 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 28 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 28 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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 type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" 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 28 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

	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 SEP 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	97.2 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input 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 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 type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Mar 2021 17:50:32

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 13:31:52

Generated On: 10 Jun 2021 10:22:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:41 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:41
Height (<i>xxx.x</i>)	68.0 in
Weight (<i>xxx.x</i>)	232.2 lb
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

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: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3922067

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3922067

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 16:45:11

Generated On: 10 Jun 2021 10:22:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3922067

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:58
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3922067

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

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:22:31

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3922067

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

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) 19 JAN 2021

What was the treatment time? (00:00-23:59) 16:34 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 16:34

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

US3922067

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

15:45 (24 HR)

Collection date and time (derived)

19 JAN 2021 15:45

US3922067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	15:58
Collection Date and Time (derived)	19 JAN 2021 15:58

US3922067

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:33:39

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3922067

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

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)	03 MAR 2021
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 12:07
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

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)	03 MAR 2021
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 13:13
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3922067

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3922067

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

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) 03 MAR 2021

What was the treatment time? (00:00-23:59) 12:36 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 12:36

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

US3922067

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3922067

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 22:36:47

Generated On: 10 Jun 2021 10:22:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922067

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Apr 2021 13:04:35

Generated On: 10 Jun 2021 10:22:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Apr 2021 13:04:35

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 10:20
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3922067

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Apr 2021 13:04:35

Generated On: 10 Jun 2021 10:22:24

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.

US3922067

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Apr 2021 13:04:35

Generated On: 10 Jun 2021 10:22:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	13 APR 2021 10:30

US3922067

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID	USA-US212-2020-MRNA-1273-P30 1000001
Adverse event	CONFUSION
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	07 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	09 SEP 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) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

PT REPORTED ON 9/8/2020 THAT SHE WAS IN HOSPITAL FOR CONFUSION THAT HAPPENED ON 9/7/2020 AROUND 18:00. WILL KNOW MORE PENDING MEDICAL RECORDS. UPDATE 10SEP2020 PATIENT REPORTED SHE WAS DISCHARGED FROM HOSPITAL ON 09SEP. NO DIAGNOSIS WAS MADE. UNKNOWN TESTS WERE DONE. PATIENT WAS TOLD BY HOSPITAL DOCTOR TO SEE HER NEUROLOGIST AND NOT TO DRIVE BECAUSE THEY THOUGHT SHE MIGHT HAVE HAD A STROKE (NOT CONFIRMED). PATIENT SAW NEUROLOGIST ON 10SEP2020. NEUROLOGIST COULD NOT ASSESS WITHOUT SEEING TEST RESULTS FROM HOSPITAL. NEUROLOGIST PLANS TO GET HOSPITAL RECORDS AND SCHEDULE 72 HOUR EEG FOR 25 OR 26SEP2020. PATIENT REPORTED SHE IS FEELING BETTER BUT TIRED AND A LITTLE "OUT OF BREATH." SHE STATED THAT SHE COULD NOT REMEMBER ABOUT 7 HOURS OF MONDAY 07SEP2020. SITE IS REQUESTING MEDICAL RECORDS. 72 HOUR EEG DONE AND RESULTS WERE NORMAL.

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

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	28 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 (4)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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)	

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	28 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 (5)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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 (6)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID

Adverse event

WORSENING OF CHRONIC
RECURRENT URINARY TRACT
INFECTION

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)

27 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)

04 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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 (7)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 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)	28 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 (7)

Data signed: (b) (4) 22 Apr 2021 21:55:38

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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)	0

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 21:55:38

Generated On: 10 Jun 2021 10:22:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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 (2)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	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 (3)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 (3)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	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 (4)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication DYMISTA
(AZCLASTINE/FLUTICSONE)

Prophylaxis Yes ☐
No ☒

Indication CHRONIC ALLERGIES
(CHEMICAL)

Dose per administration 137/50

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 (4)

Data signed: (b) (4) 01 Apr 2021 16:19:09

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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 (6)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication OMEGA 3

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 (6)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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 (7)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication GRAPSEED EXTRACT
WITH RESVERATROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 12.5MG/15MG

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 (7)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	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) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication COQ10

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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"/>

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication CRANBERRY

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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"/>

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

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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US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication MACROBID

Prophylaxis Yes ☐
No ☒

Indication AE#6 WORSENING CHRONIC
RECURRENT URINARY TRACT
INFECTIONS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	27 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)	05 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication ONDANSETRON HCL/ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA/VOMITING (AE 4/5)

Dose per administration 8

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) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
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 (13)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication	IV HYDRATION
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NAUSEA/VOMITING/DIARRHEA (AE 4,5,6)
Dose per administration	300
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

Name of Medication ROCEPHIN (CEFTRIAXONE)

Prophylaxis Yes ☐
No ☒

Indication AE#6 WORSENING OF CHRONIC
RECURRENT URINARY TRACT
INFECTIONS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 16:19:09

Generated On: 10 Jun 2021 10:22:24

	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)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 20:33:37

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
07 SEP 2020	CT CHEST	Adverse Event	
07 SEP 2020	CT SCAN OF HEAD	Adverse Event	
27 SEP 2020	EEG(72 HOURS)	Adverse Event	
08 SEP 2020	MRI HEAD	Adverse Event	
08 SEP 2020	EEG	Adverse Event	
08 SEP 2020	EEG	Adverse Event	

US3922067

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Mar 2021 13:01:22

Generated On: 10 Jun 2021 10:22:24

Date of dosing discontinuation (dd MMM yyyy)	29 OCT 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input checked="" type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Due to SARS-COV-2 <input type="checkbox"/>
	Other <input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SAE #1
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US3922067

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:22:24

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 ☐

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	10/SEP/2020 14:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/SEP/2020 08:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	11/SEP/2020 11:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	28/SEP/2020 11:09
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

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	07/OCT/2020 09:28
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

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	14/OCT/2020 09:39
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

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/OCT/2020 18:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	02/NOV/2020 20:40
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

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	04/NOV/2020 08:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 22 Feb 2021 20:33:38

Generated On: 10 Jun 2021 10:22:24

SAEID	USA-US212-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHELE
Investigator's Last Name	REYNOLDS
Site Address: Street	9 MEDICAL PKWY SUITE 202
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75234
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:13
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

US3922067 (Prod: Synexus Clinical Research US, Inc. - Dallas)

US3922067

Form: Participant Creation

Generated On: 10 Jun 2021 10:22:24

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'US3922067'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:58

US3922067

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	01 Sep 2020 18:25:43

US3922067

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:59

US3922067

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Clinic (Clinic)'	Cristina Puig (b) (4)	01 Sep 2020 18:25:43

US3922067

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'SCRN'	System	01 Sep 2020 18:25:43

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per GCL Lab Recon : it appears GCL has year of birth as 1945 and Sex as Male and EDC has 1943 and Sex as Female. Please review and advise if 1943 and Sex of Female is correct. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:33:16
Query 'Per GCL Lab Recon : it appears GCL has yearlyn yauch of birth as 1945 and Sex as Male and EDC has 1943 and Sex as Female. Please review and advise if 1943 and Sex of Female is correct. ' answered with 'subject is Female, YOB=1943, site will request lab to correct/update labs' (Site from DM).	(b) (4) (b) (4)	20 Oct 2020 17:59:40
User opened query 'Per GCL Lab Recon : it appears GCL has year of birth as 1945 and Sex as Male and EDC has 1943 and Sex as Female. Please review and advise if 1943 and Sex of Female is correct. ' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 20:52:23
Query 'Per GCL Lab Recon : it appears GCL has year of birth as 1945 and EDC has 1943. Please review and advise if 1943 is correct.' canceled (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 20:48:27
User opened query 'Per GCL Lab Recon : it appears GCL has year of birth as 1945 and EDC has 1943. Please review and advise if 1943 is correct.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 20:48:17
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:55:00

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '77'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'YEARS'	System	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '77'	System	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per GCL Lab Recon: Central Laboratory - Nasopharyngeal Swab for Visit1 Day1: GCL has sex as MALE, however EDC has sex reported as FEMALE. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:19:43
Query 'Per GCL Lab Recon: Central Laboratory - Nasopharyngeal Swab for Visit1 Day1: GCL has sex as MALE, however EDC has sex reported as FEMALE. Please review and reconcile.' answered with 'per source, subject is FEMALE, site will submit change request to lab' (Site from DM).	lynn yauch (b) (4) (b) (4)	29 Oct 2020 13:31:08
User opened query 'Per GCL Lab Recon: Central Laboratory - Nasopharyngeal Swab for Visit1 Day1: GCL has sex as MALE, however EDC has sex reported as FEMALE. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:13:01
User entered 'Female (F)'	Jacklyn Newton (b) (4) (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Jacklyn Newton (b) (4)	02 Sep 2020 17:58:30

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:42:17
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	05 Nov 2020 14:56:55
User entered '01 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	05 Nov 2020 14:56:48
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:03:31
User entered '1 Sep 2020'	Cristina Puig (b) (4) (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2020'	System	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2020'	System	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Amendment 3 (3)'	Cristina Puig (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Cristina Puig (b) (4)	01 Sep 2020 18:27:24
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	01 Sep 2020 18:26:52

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 18:27:24
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	01 Sep 2020 18:26:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 15:54:59

US3922067

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'I'	System	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:22:24

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:22:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:33:53

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:39:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:39:40
Data point term sent to Coder	System	24 Nov 2020 20:37:56
Coding entries removed.	lynn yauch (b) (4)	24 Nov 2020 20:37:37
User entered 'HYPOthyroidism' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Nov 2020 20:37:37
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:35:46
Data point term sent to Coder	System	04 Sep 2020 19:34:45
User entered 'hyperthyroidism'	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:07

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:35:46
Data point term sent to Coder	System	04 Sep 2020 19:34:45
User entered 'hypercholesterolemia'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2003'	Cristina Puig (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2003'	System	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2003'	System	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:21

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:35:46
Data point term sent to Coder	System	04 Sep 2020 19:34:45
User entered 'atrial fibrillation'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2015'	Cristina Puig (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2015'	System	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2015'	System	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:38

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to chemicals, LLT: Allergy to chemicals NOS - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 12:51:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 12:51:18
User closed query 'Per DM CLR: Please specify the type of ALLERGIES (e.g. Seasonal Allergies, Medication Allergy, Food Allergy etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:15:58
Data point term sent to Coder	System	20 Oct 2020 20:25:34
Coding entries removed.	Pauline Jackson (b) (4)	20 Oct 2020 20:24:37
User entered 'CHRONIC ALLERGIES (chemical)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	20 Oct 2020 20:24:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 20:04:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 20:04:43
Data point term sent to Coder	System	20 Oct 2020 20:03:36
Query 'Per DM CLR: Please specify the type of ALLERGIES (e.g. Seasonal Allergies, Medication Allergy, Food Allergy etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4)	20 Oct 2020 20:03:14
Coding entries removed.	Pauline Jackson (b) (4)	20 Oct 2020 20:03:07
User entered 'CHRONIC ALLERGIES (seasonal)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	20 Oct 2020 20:03:07

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the type of ALLERGIES (e.g. Seasonal Allergies, Medication Allergy, Food Allergy etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:13:01
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Sep 2020 18:03:42
Data point term sent to Coder	System	11 Sep 2020 18:02:29
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:01:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Sep 2020 18:01:46
Query 'For coding purposes, please enter the type of CHRONIC ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' canceled (Site from System).	Coder Import (b) (4)	11 Sep 2020 18:01:39
User opened query 'For coding purposes, please enter the type of CHRONIC ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' (Site from System).	Coder Import (b) (4)	07 Sep 2020 21:55:29
Data point term sent to Coder	System	04 Sep 2020 19:35:48
User entered 'chronic allergies'	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1998'	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1998'	System	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1998'	System	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:34:57

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:37:48
Data point term sent to Coder	System	04 Sep 2020 19:36:50
User entered 'left breast cancer'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2004'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '21 Jan 2005'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2004'	System	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2004'	System	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2005'	System	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2005'	System	04 Sep 2020 19:36:16

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:37:47
Data point term sent to Coder	System	04 Sep 2020 19:36:51
User entered 'menorrhagia'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1982'	Cristina Puig (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1982'	Cristina Puig (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1982'	System	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1982'	System	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1982'	System	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1982'	System	04 Sep 2020 19:36:37

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:38:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:38:39
Data point term sent to Coder	System	04 Sep 2020 19:37:52
User entered 'tonsillitis'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Dec 1953'	Cristina Puig (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Dec 1953'	Cristina Puig (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 1953'	System	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1953'	System	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 1953'	System	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1953'	System	04 Sep 2020 19:37:03

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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)	04 Sep 2020 19:39:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:39:41
Data point term sent to Coder	System	04 Sep 2020 19:38:54
User entered 'osteoarthritis bilateral hands'	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2015'	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2015'	System	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2015'	System	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:37:59

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:43:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:43:47
Data point term sent to Coder	System	04 Sep 2020 19:43:06
User entered 'sleep apnea'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2008'	Cristina Puig (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2008'	System	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2008'	System	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	04 Sep 2020 19:42:07

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:45:51
Data point term sent to Coder	System	04 Sep 2020 19:44:08
User entered 'bilateral cataracts'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Cristina Puig (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Cristina Puig (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	04 Sep 2020 19:43:15

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 21:59:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:59:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:46:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:46:53
Data point term sent to Coder	System	04 Sep 2020 19:45:12
User entered 'bilateral cataract surgery'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Cristina Puig (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Cristina Puig (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	04 Sep 2020 19:45:04

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy (breast cancer) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 00:44:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 00:44:56
User closed query 'Per DM CLR: Please update the procedure to confirm if the removed LUMP was benign or cancerous. Review and update medical history as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	03 Nov 2020 18:12:19
' (Site from DM).		
Query 'Per DM CLR: Please update the procedure to confirm if the removed LUMP was benign or cancerous. Review and update medical history as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Lorine Cook (b) (4)	30 Oct 2020 20:02:34
' answered with 'See #5 of Medical HX' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	30 Oct 2020 20:02:27
Coding entries removed.	Lorine Cook (b) (4)	30 Oct 2020 20:02:15
User entered 'LUMPECTOMY LEFT BREAST(Cancerous)' reason for change: Data Entry Error	Lorine Cook (b) (4)	30 Oct 2020 20:02:15
User opened query 'Per DM CLR: Please update the procedure to confirm if the removed LUMP was benign or cancerous. Review and update medical history as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Oct 2020 16:10:26
' (Site from DM).		

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:46:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 19:46:54
Data point term sent to Coder	System	04 Sep 2020 19:46:13
User entered 'lumpectomy left breast'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36
	(b) (4)	

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '21 Jan 2005'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '21 Jan 2005'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2005'	System	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2005'	System	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2005'	System	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2005'	System	04 Sep 2020 19:45:36

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:09:21
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:31:28
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:31:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Urinary bladder suspension, LLT: Bladder suspension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:47:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:47:41
Data point term sent to Coder	System	04 Sep 2020 19:47:17
User entered 'bladder suspension'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '05 Sep 2001'	Cristina Puig (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '05 Sep 2001'	Cristina Puig (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2001'	System	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2001'	System	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2001'	System	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2001'	System	04 Sep 2020 19:47:06

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:48:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:48:48
Data point term sent to Coder	System	04 Sep 2020 19:48:18
User entered 'hysterectomy'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please note, Start date of MH = 12 MAR 1982. However, Surgically Sterile date recorded in Childbearing eCRF is UN UNK 1982. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:53:19
Query 'Per DM CLR: Please note, Start date of MH = Pauline Jackson 12 MAR 1982. However, Surgically Sterile date recorded in Childbearing eCRF is UN UNK 1982. Review if this should be reconciled. Else, Please clarify dates.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:36:33
User opened query 'Per DM CLR: Please note, Start date of MH = 12 MAR 1982. However, Surgically Sterile date recorded in Childbearing eCRF is UN UNK 1982. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:34:46
User entered '12 Mar 1982'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '12 Mar 1982'	Cristina Puig (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Mar 1982'	System	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1982'	System	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Mar 1982'	System	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1982'	System	04 Sep 2020 19:47:27

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:48:47
Data point term sent to Coder	System	04 Sep 2020 19:48:18
User entered 'tubal ligation'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Jun 1973'	Cristina Puig (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Jun 1973'	Cristina Puig (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jun 1973'	System	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1973'	System	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jun 1973'	System	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1973'	System	04 Sep 2020 19:48:06

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast neoplasm removal, PT: Breast cyst excision, LLT: Breast cyst excision - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Sep 2020 07:16:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:16:44
Data point term sent to Coder	System	04 Sep 2020 19:49:19
User entered 'right breast cyst removal benign'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1975'	Cristina Puig (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1975'	Cristina Puig (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1975'	System	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1975'	System	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1975'	System	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1975'	System	04 Sep 2020 19:48:42

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:54:37
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:40:49
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:36:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:50:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:50:49
Data point term sent to Coder	System	04 Sep 2020 19:49:22
User entered 'left knee replacement'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '07 Jun 2018'	Cristina Puig (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '07 Jun 2018'	Cristina Puig (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jun 2018'	System	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2018'	System	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jun 2018'	System	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2018'	System	04 Sep 2020 19:49:14

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:09:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:40:56
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:36:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:53:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:53:47
Data point term sent to Coder	System	04 Sep 2020 19:52:28
User entered 'right shoulder replacement'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '30 Dec 2011'	Cristina Puig (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '30 Dec 2011'	Cristina Puig (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 2011'	System	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 2011'	System	04 Sep 2020 19:51:50

US3922067

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	04 Sep 2020 19:51:50

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:09:57
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:41:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:36:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:53:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:53:48
Data point term sent to Coder	System	04 Sep 2020 19:52:28
User entered 'left shoulder replacement'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:52:19

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '09 Sep 2011'	Cristina Puig (b) (4)	04 Sep 2020 19:52:19

US3922067

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:52:19

US3922067

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:52:19

US3922067

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '09 Sep 2011'	Cristina Puig (b) (4)	04 Sep 2020 19:52:19

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:52:19

US3922067

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2011'	System	04 Sep 2020 19:52:19

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	04 Sep 2020 19:52:19

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2011'	System	04 Sep 2020 19:52:19

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	04 Sep 2020 19:52:19

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 19:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:55:48
Data point term sent to Coder	System	04 Sep 2020 19:54:30
User entered 'tonsillectomy'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Dec 1953'	Cristina Puig (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un Dec 1953'	Cristina Puig (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 1953'	System	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1953'	System	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 1953'	System	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1953'	System	04 Sep 2020 19:53:33

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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)	12 Oct 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:16:35
Data point term sent to Coder	System	12 Oct 2020 15:15:29
User entered 'fatigue'	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2018'	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2018'	System	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2018'	System	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	12 Oct 2020 15:14:34

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Oct 2020 20:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:33:37
Data point term sent to Coder	System	20 Oct 2020 20:32:55
User entered 'urinary incontinence'	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:32:26

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Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'UN UNK 2001' reason for change:	(b) (4)	
Data Entry Error	Pauline Jackson (b) (4)	20 Oct 2020 20:32:49
User entered 'un UNK 2003'	(b) (4)	
	Pauline Jackson (b) (4)	20 Oct 2020 20:32:26
	(b) (4)	

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Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Pauline Jackson (b) (4)	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'UN UNK 2001' reason for change:	(b) (4)	
Data Entry Error	Pauline Jackson (b) (4)	20 Oct 2020 20:32:49
User entered 'un UNK 2003'	(b) (4)	
	Pauline Jackson (b) (4)	20 Oct 2020 20:32:26
	(b) (4)	

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2001'	System	20 Oct 2020 20:32:49
User entered 'Jan 2003'	System	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2001'	System	20 Oct 2020 20:32:49
User entered '2003'	System	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2001'	System	20 Oct 2020 20:32:49
User entered 'Jan 2003'	System	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2001'	System	20 Oct 2020 20:32:49
User entered '2003'	System	20 Oct 2020 20:32:26

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Oct 2020 20:39:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:39:41
Data point term sent to Coder	System	20 Oct 2020 20:38:02
User entered 'left shoulder pain'	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2011'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '09 Sep 2011'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2011'	System	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Sep 2011'	System	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	20 Oct 2020 20:38:02

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:39:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:39:43
Data point term sent to Coder	System	20 Oct 2020 20:39:03
User entered 'right shoulder pain'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2011'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '30 Dec 2011'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2011'	System	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Dec 2011'	System	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2011'	System	20 Oct 2020 20:38:25

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:40:44
Data point term sent to Coder	System	20 Oct 2020 20:40:08
User entered 'left knee pain'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2018'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2018'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Pauline Jackson (b) (4)	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2018'	System	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2018'	System	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2018'	System	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2018'	System	20 Oct 2020 20:39:20

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:13:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:44
Data point term sent to Coder	System	30 Oct 2020 20:46:55
User entered 'Dizziness'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2013'	Lorine Cook (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2013'	System	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2013'	System	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:46:12

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:34:12
Query 'Per DM CLR: Please note that there is no Con lynn yauch Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'subject takes medication as prescribed when needed, no ongoing CM for this indication' (Site from DM).	(b) (4) (b) (4)	18 Jan 2021 19:28:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:40:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Chronic UTI - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:21:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:21:09
Data point term sent to Coder	System	30 Oct 2020 20:47:56
User entered 'Chronic Recurrent UTI's'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Un UNK 2010'	Lorine Cook (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:47:17

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:13:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:50
Data point term sent to Coder	System	30 Oct 2020 20:49:59
User entered 'Chronic Shortness of breath'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2017'	Lorine Cook (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2017'	System	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2017'	System	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:49:20

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Caffeine allergy, LLT: Caffeine allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Oct 2020 11:26:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:26:13
Data point term sent to Coder	System	30 Oct 2020 20:50:59
User entered 'Allergy of Caffeine'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Un UNK 1980'	Lorine Cook (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1980'	System	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1980'	System	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:50:05

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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.	(b) (4) Coder Import (b) (4)	10 Nov 2020 13:13:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:13:32
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) (b) (4)	30 Oct 2020 21:13:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:55
Data point term sent to Coder	System	30 Oct 2020 20:52:00
User entered 'Allergy to ciprofloxacin'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Un UNK 2010'	Lorine Cook (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:51:33

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:13:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:13:58
Data point term sent to Coder	System	30 Oct 2020 20:53:02
User entered 'Allergy to erythromycin'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1997'	Lorine Cook (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1997'	System	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1997'	System	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:52:46

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:14:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 21:14:07
Data point term sent to Coder	System	30 Oct 2020 20:58:11
User entered 'Allergy to nitrofurantoin'	Lorine Cook (b) (4)	30 Oct 2020 20:57:15
	(b) (4)	

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2005'	Lorine Cook (b) (4)	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2005'	System	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2005'	System	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:57:15

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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: Penicillin allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:14:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:07
Data point term sent to Coder	System	30 Oct 2020 20:58:11
User entered 'Allergy to penicillin'	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 1950'	Lorine Cook (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Lorine Cook (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2000'	Lorine Cook (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 1950'	System	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1950'	System	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2000'	System	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2000'	System	30 Oct 2020 20:57:55

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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.	(b) (4) Coder Import (b) (4)	30 Oct 2020 21:14:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:14:32
Data point term sent to Coder	System	30 Oct 2020 20:59:12
User entered 'Allergy to Septra'	Lorine Cook (b) (4)	30 Oct 2020 20:58:28
	(b) (4)	

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'un UNK 2010'	Lorine Cook (b) (4)	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Lorine Cook (b) (4)	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2010'	System	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2010'	System	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	30 Oct 2020 20:58:28

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Dysphagia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Apr 2021 15:49:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 15:49:17
Data point term sent to Coder	System	16 Apr 2021 15:47:59
User entered 'dysphagia'	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	(b) (4) lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User entered 'un UNK 2019'	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:17
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'Jan 2019'	System	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '2019'	System	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 10:22:24

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered empty.	System	16 Apr 2021 15:47:23
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	16 Apr 2021 15:45:45
DataPoint inactivated with code reason code Data not required.	lynn yauch (b) (4)	03 Nov 2020 18:14:48

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '11:47'	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '1 Sep 2020 11:47'	System	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '68.0' in	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 19:55:27
DataPoint set to visible.	(b) (4) System	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '236.6' lb	Cristina Puig (b) (4)	04 Sep 2020 19:55:27
DataPoint set to visible.	System	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered '36.05013'	System	04 Sep 2020 19:55:27
DataPoint set to visible.	System	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'kg/m2'	System	04 Sep 2020 19:55:27
DataPoint set to visible.	System	01 Sep 2020 18:27:51

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'bpm'	System	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'breaths/min'	System	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'mmHg'	System	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User entered 'mmHg'	System	04 Sep 2020 19:55:27

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32

US3922067

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32

US3922067

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 19:55:59

US3922067

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 19:55:59

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Surgically sterile (SURGICALLY STERILE)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '12 Mar 1982' reason for change: Data Entry Error	(b) (4)	
	Pauline Jackson (b) (4)	20 Oct 2020 20:36:12
User entered 'un UNK 1982'	(b) (4)	
	Cristina Puig (b) (4)	04 Sep 2020 19:58:00
	(b) (4)	

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

US3922067

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:24

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:00

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Folder: Screening

Form: Risk of Exposure

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 19:58:31

US3922067

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	01 Sep 2020 18:29:24

US3922067

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:01:44
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' answered with 'Corrected' (Site from DM).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:35:30
User entered '01 Sep 2020' reason for change: Per Query Resolution	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:35:22
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:42:57
User entered '1 Sep 2020'	Cristina Puig (b) (4) (b) (4)	01 Sep 2020 18:29:24

US3922067

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Clinic (Clinic)'	Cristina Puig (b) (4)	01 Sep 2020 18:29:24

US3922067

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'VISIT1'	System	01 Sep 2020 18:29:24

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:29:33

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '189194'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:29:33

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:29:33

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

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)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 05:58:28
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated' (Site from DM).	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:00:03
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 19:59:39
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:45:58

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

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)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:59:39

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 19:59:55
User entered 'No (N)' reason for change: Data Entry Error	System	04 Sep 2020 19:59:55
User opened query 'Data is required. Please complete.' (Site from System).	Cristina Puig (b) (4)	04 Sep 2020 19:59:55
User entered empty.	(b) (4)	
	System	04 Sep 2020 19:59:39
	Cristina Puig (b) (4)	04 Sep 2020 19:59:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:59:39

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 19:59:39

US3922067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:24

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	06 Oct 2020 20:36:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:56:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:56:16

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Pre-Dose (PREDOSE)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '11:47'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '1 Sep 2020 11:47'	System	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.4' F	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Oral (Oral)'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '63'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'bpm'	System	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'breaths/min'	System	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '128'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'mmHg'	System	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '70'	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'mmHg'	System	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Cristina Puig (b) (4)	04 Sep 2020 20:01:08

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Post-Dose (POSTDOSE)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14:54'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '1 Sep 2020 14:54'	System	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.7' F	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Oral (Oral)'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '58'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'bpm'	System	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'breaths/min'	System	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '126'	Cristina Puig (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'mmHg'	System	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:10:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is, per PI within normal limits' (Site from System).	lynn yauch (b) (4) (b) (4)	17 Sep 2020 13:57:29
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:24:23
User entered '56'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'mmHg'	System	04 Sep 2020 20:01:49

US3922067

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:02:08

US3922067

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:02:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Chana Hines (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Chana Hines (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

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 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Chana Hines (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:01:34
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' answered with 'Corrected' (Site from DM).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:34:55
User entered '01 Sep 2020' reason for change: Per Query Resolution	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:34:45
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:43:12
User entered '1 Sep 2020'	Chana Hines (b) (4) (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14:05'	Chana Hines (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '01 Sep 2020 14:05'	System	05 Nov 2020 23:34:45
User entered '1 Sep 2020 14:05'	System	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Right Arm (RIGHT ARM)'	Chana Hines (b) (4)	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'ONCE'	System	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 19:57:08

US3922067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:03:59

US3922067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 20:03:59

US3922067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '11:54'	Cristina Puig (b) (4)	04 Sep 2020 20:03:59

US3922067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '1 Sep 2020 11:54'	System	04 Sep 2020 20:03:59

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1 Sep 2020'	Cristina Puig (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '13:07'	Cristina Puig (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '1 Sep 2020 13:07'	System	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	04 Sep 2020 20:04:13

US3922067

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:04:25

US3922067

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	04 Sep 2020 20:04:25

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:03:54', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fefe63-dfdc-4449-a996-520b2252a897'	System	01 Sep 2020 20:04:10
User entered 'Yes (Y)'	System	01 Sep 2020 20:04:10

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:03:39', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fefe63-dfdc-4449-a996-520b2252a897'	System	01 Sep 2020 20:04:10
User entered '97.7'	System	01 Sep 2020 20:04:10

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:03:43', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fefe63-dfdc-4449-a996-520b2252a897'	System	01 Sep 2020 20:04:10
User entered 'No (N)'	System	01 Sep 2020 20:04:10

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fefe63-dfdc-4449-a996-520b2252a897'	System	01 Sep 2020 20:04:10
User entered '01 Sep 2020 15:04'	System	01 Sep 2020 20:04:10

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 14:25'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 16:55'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:15:37', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c50f3b51-9f65-4fa9-b530-f0018af17877'	System	02 Sep 2020 04:16:03
User entered 'Yes (Y)'	System	02 Sep 2020 04:16:03

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:15:46', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c50f3b51-9f65-4fa9-b530-f0018af17877'	System	02 Sep 2020 04:16:03
User entered '97.2'	System	02 Sep 2020 04:16:03

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:15:50', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c50f3b51-9f65-4fa9-b530-f0018af17877'	System	02 Sep 2020 04:16:03
User entered 'No (N)'	System	02 Sep 2020 04:16:03

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:15:59', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c50f3b51-9f65-4fa9-b530-f0018af17877'	System	02 Sep 2020 04:16:03
User entered '01 Sep 2020 23:15'	System	02 Sep 2020 04:16:03

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 17:50'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 2'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:54:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '81436cc6-1dbe-4b4b-8f21-e334e7634154'	System	03 Sep 2020 01:54:25
User entered 'Yes (Y)'	System	03 Sep 2020 01:54:25

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:54:11', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '81436cc6-1dbe-4b4b-8f21-e334e7634154'	System	03 Sep 2020 01:54:25
User entered '97.3'	System	03 Sep 2020 01:54:25

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:54:16', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '81436cc6-1dbe-4b4b-8f21-e334e7634154'	System	03 Sep 2020 01:54:25
User entered 'No (N)'	System	03 Sep 2020 01:54:25

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:54:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '81436cc6-1dbe-4b4b-8f21-e334e7634154'	System	03 Sep 2020 01:54:25
User entered '02 Sep 2020 20:54'	System	03 Sep 2020 01:54:25

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 3'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-04T00:24:57', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0049cea3-3d66-4b8d-ba69-5d900465b4ce'	System	04 Sep 2020 05:25:19
User entered 'Yes (Y)'	System	04 Sep 2020 05:25:19

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-04T00:25:06', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0049cea3-3d66-4b8d-ba69-5d900465b4ce' User entered '97.5'	System	04 Sep 2020 05:25:19
	System	04 Sep 2020 05:25:19

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-04T00:25:10', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0049cea3-3d66-4b8d-ba69-5d900465b4ce'	System	04 Sep 2020 05:25:19
User entered 'No (N)'	System	04 Sep 2020 05:25:19

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-04T00:25:16', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0049cea3-3d66-4b8d-ba69-5d900465b4ce'	System	04 Sep 2020 05:25:19
User entered '04 Sep 2020 00:25'	System	04 Sep 2020 05:25:19

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 4'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:45:39', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '8bec4142-9e0c-43f2-9030-bedab0c94dd8'	System	05 Sep 2020 06:46:20
User entered 'Yes (Y)'	System	05 Sep 2020 06:46:20

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:06', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '8bec4142-9e0c-43f2-9030-bedab0c94dd8'	System	05 Sep 2020 06:46:20
User entered '97.2'	System	05 Sep 2020 06:46:20

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:09', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '8bec4142-9e0c-43f2-9030-bedab0c94dd8'	System	05 Sep 2020 06:46:20
User entered 'No (N)'	System	05 Sep 2020 06:46:20

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:15', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '8bec4142-9e0c-43f2-9030-bedab0c94dd8'	System	05 Sep 2020 06:46:20
User entered '05 Sep 2020 01:46'	System	05 Sep 2020 06:46:20

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 5'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:04:42', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a6506634-0333-479c-bc11-dfcc0d1863e3'	System	06 Sep 2020 05:05:04
User entered 'Yes (Y)'	System	06 Sep 2020 05:05:04

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:04:50', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a6506634-0333-479c-bc11-dfcc0d1863e3'	System	06 Sep 2020 05:05:04
User entered '97.6'	System	06 Sep 2020 05:05:04

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:04:54', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a6506634-0333-479c-bc11-dfcc0d1863e3'	System	06 Sep 2020 05:05:04
User entered 'No (N)'	System	06 Sep 2020 05:05:04

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:04:59', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a6506634-0333-479c-bc11-dfcc0d1863e3'	System	06 Sep 2020 05:05:04
User entered '06 Sep 2020 00:04'	System	06 Sep 2020 05:05:04

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 6'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:35:51', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0c8aa24e-d84b-4d83-870f-3e2f668c20f3'	System	07 Sep 2020 04:36:12
User entered 'Yes (Y)'	System	07 Sep 2020 04:36:12

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:35:57', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0c8aa24e-d84b-4d83-870f-3e2f668c20f3'	System	07 Sep 2020 04:36:12
User entered '97.6'	System	07 Sep 2020 04:36:12

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:01', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0c8aa24e-d84b-4d83-870f-3e2f668c20f3'	System	07 Sep 2020 04:36:12
User entered 'No (N)'	System	07 Sep 2020 04:36:12

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:07', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0c8aa24e-d84b-4d83-870f-3e2f668c20f3'	System	07 Sep 2020 04:36:12
User entered '06 Sep 2020 23:36'	System	07 Sep 2020 04:36:12

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 7'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:34', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9a6a992e-c93e-488d-b117-ba6d99e5e8b6'	System	08 Sep 2020 05:46:45
User entered 'Yes (Y)'	System	08 Sep 2020 05:46:45

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9a6a992e-c93e-488d-b117-ba6d99e5e8b6'	System	08 Sep 2020 05:46:45
User entered '97.5'	System	08 Sep 2020 05:46:45

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:26', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9a6a992e-c93e-488d-b117-ba6d99e5e8b6'	System	08 Sep 2020 05:46:45
User entered 'No (N)'	System	08 Sep 2020 05:46:45

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:39', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9a6a992e-c93e-488d-b117-ba6d99e5e8b6'	System	08 Sep 2020 05:46:45
User entered '08 Sep 2020 00:46'	System	08 Sep 2020 05:46:45

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:22', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '39fcaaf9-2558-419d-8155-1688742790fc'	System	01 Sep 2020 20:04:58
User entered 'None (1)'	System	01 Sep 2020 20:04:58

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:33', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '39fcaaf9-2558-419d-8155-1688742790fc'	System	01 Sep 2020 20:04:58
User entered 'No (N)'	System	01 Sep 2020 20:04:58

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:37', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '39fcaaf9-2558-419d-8155-1688742790fc'	System	01 Sep 2020 20:04:58
User entered 'No (N)'	System	01 Sep 2020 20:04:58

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:46', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '39fcaaf9-2558-419d-8155-1688742790fc'	System	01 Sep 2020 20:04:58
User entered 'None (1)'	System	01 Sep 2020 20:04:58

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:04:56', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '39fcaaf9-2558-419d-8155-1688742790fc'	System	01 Sep 2020 20:04:58
User entered '01 Sep 2020 15:04'	System	01 Sep 2020 20:04:58

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 14:25'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 16:55'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:19', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e0bfa5ef-68e4-476a-aea3-a5153444c22a'	System	02 Sep 2020 04:10:02
User entered 'None (1)'	System	02 Sep 2020 04:10:02

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:42', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e0bfa5ef-68e4-476a-aea3-a5153444c22a'	System	02 Sep 2020 04:10:02
User entered 'No (N)'	System	02 Sep 2020 04:10:02

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:46', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e0bfa5ef-68e4-476a-aea3-a5153444c22a'	System	02 Sep 2020 04:10:02
User entered 'No (N)'	System	02 Sep 2020 04:10:02

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:50', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e0bfa5ef-68e4-476a-aea3-a5153444c22a'	System	02 Sep 2020 04:10:02
User entered 'None (1)'	System	02 Sep 2020 04:10:02

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:59', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e0bfa5ef-68e4-476a-aea3-a5153444c22a'	System	02 Sep 2020 04:10:02
User entered '01 Sep 2020 23:09'	System	02 Sep 2020 04:10:02

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 17:50'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 2'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:50:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0dd83848-9128-4276-ad69-8f0fb8f05f38'	System	03 Sep 2020 01:51:07
User entered 'None (1)'	System	03 Sep 2020 01:51:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:50:48', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0dd83848-9128-4276-ad69-8f0fb8f05f38'	System	03 Sep 2020 01:51:07
User entered 'No (N)'	System	03 Sep 2020 01:51:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:50:52', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0dd83848-9128-4276-ad69-8f0fb8f05f38'	System	03 Sep 2020 01:51:07
User entered 'No (N)'	System	03 Sep 2020 01:51:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:50:56', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0dd83848-9128-4276-ad69-8f0fb8f05f38'	System	03 Sep 2020 01:51:07
User entered 'None (1)'	System	03 Sep 2020 01:51:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0dd83848-9128-4276-ad69-8f0fb8f05f38'	System	03 Sep 2020 01:51:07
User entered '02 Sep 2020 20:51'	System	03 Sep 2020 01:51:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 3'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:13', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'ca0a2c4e-7082-4398-aab8-fa20dce08dcf'	System	04 Sep 2020 02:35:38
User entered 'None (1)'	System	04 Sep 2020 02:35:38

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:19', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'ca0a2c4e-7082-4398-aab8-fa20dce08dcf'	System	04 Sep 2020 02:35:38
User entered 'No (N)'	System	04 Sep 2020 02:35:38

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:22', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'ca0a2c4e-7082-4398-aab8-fa20dce08dcf'	System	04 Sep 2020 02:35:38
User entered 'No (N)'	System	04 Sep 2020 02:35:38

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:27', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'ca0a2c4e-7082-4398-aab8-fa20dce08dcf'	System	04 Sep 2020 02:35:38
User entered 'None (1)'	System	04 Sep 2020 02:35:38

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'ca0a2c4e-7082-4398-aab8-fa20dce08dcf'	System	04 Sep 2020 02:35:38
User entered '03 Sep 2020 21:35'	System	04 Sep 2020 02:35:38

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 4'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:20', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7ecc8a3f-0da3-41ec-a336-226c7f252c7b'	System	05 Sep 2020 06:46:41
User entered 'None (1)'	System	05 Sep 2020 06:46:41

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:24', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7ecc8a3f-0da3-41ec-a336-226c7f252c7b'	System	05 Sep 2020 06:46:41
User entered 'No (N)'	System	05 Sep 2020 06:46:41

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:27', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7ecc8a3f-0da3-41ec-a336-226c7f252c7b'	System	05 Sep 2020 06:46:41
User entered 'No (N)'	System	05 Sep 2020 06:46:41

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7ecc8a3f-0da3-41ec-a336-226c7f252c7b'	System	05 Sep 2020 06:46:41
User entered 'None (1)'	System	05 Sep 2020 06:46:41

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7ecc8a3f-0da3-41ec-a336-226c7f252c7b'	System	05 Sep 2020 06:46:41
User entered '05 Sep 2020 01:46'	System	05 Sep 2020 06:46:41

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 5'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:07', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dcc65b2b-1475-467c-a3d2-817a4eaf9b25'	System	06 Sep 2020 05:01:28
User entered 'None (1)'	System	06 Sep 2020 05:01:28

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:11', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dcc65b2b-1475-467c-a3d2-817a4eaf9b25'	System	06 Sep 2020 05:01:28
User entered 'No (N)'	System	06 Sep 2020 05:01:28

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dcc65b2b-1475-467c-a3d2-817a4eaf9b25'	System	06 Sep 2020 05:01:28
User entered 'No (N)'	System	06 Sep 2020 05:01:28

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:17', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dcc65b2b-1475-467c-a3d2-817a4eaf9b25'	System	06 Sep 2020 05:01:28
User entered 'None (1)'	System	06 Sep 2020 05:01:28

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:25', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dcc65b2b-1475-467c-a3d2-817a4eaf9b25'	System	06 Sep 2020 05:01:28
User entered '06 Sep 2020 00:01'	System	06 Sep 2020 05:01:28

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 6'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2e87da2b-4a44-4d08-ad18-17964d91549c'	System	07 Sep 2020 04:37:07
User entered 'None (1)'	System	07 Sep 2020 04:37:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2e87da2b-4a44-4d08-ad18-17964d91549c'	System	07 Sep 2020 04:37:07
User entered 'No (N)'	System	07 Sep 2020 04:37:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:39', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2e87da2b-4a44-4d08-ad18-17964d91549c'	System	07 Sep 2020 04:37:07
User entered 'No (N)'	System	07 Sep 2020 04:37:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:36:58', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2e87da2b-4a44-4d08-ad18-17964d91549c'	System	07 Sep 2020 04:37:07
User entered 'None (1)'	System	07 Sep 2020 04:37:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:03', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2e87da2b-4a44-4d08-ad18-17964d91549c'	System	07 Sep 2020 04:37:07
User entered '06 Sep 2020 23:37'	System	07 Sep 2020 04:37:07

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 7'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a901bb1d-9d5d-4d82-823a-391bcf8ec15b'	System	08 Sep 2020 05:47:04
User entered 'None (1)'	System	08 Sep 2020 05:47:04

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:49', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a901bb1d-9d5d-4d82-823a-391bcf8ec15b'	System	08 Sep 2020 05:47:04
User entered 'No (N)'	System	08 Sep 2020 05:47:04

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:52', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a901bb1d-9d5d-4d82-823a-391bcf8ec15b'	System	08 Sep 2020 05:47:04
User entered 'No (N)'	System	08 Sep 2020 05:47:04

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:46:55', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a901bb1d-9d5d-4d82-823a-391bcf8ec15b'	System	08 Sep 2020 05:47:04
User entered 'None (1)'	System	08 Sep 2020 05:47:04

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a901bb1d-9d5d-4d82-823a-391bcf8ec15b'	System	08 Sep 2020 05:47:04
User entered '08 Sep 2020 00:47'	System	08 Sep 2020 05:47:04

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:03', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:06', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:13', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:16', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:19', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:22', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'None (0)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:26', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered 'No (N)'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T15:05:38', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fd5ea802-946e-41a7-bdf2-f0b0e8aeb9b1'	System	01 Sep 2020 20:05:41
User entered '01 Sep 2020 15:05'	System	01 Sep 2020 20:05:41

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 14:25'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 16:55'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:25', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:36', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:39', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:44', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'None (0)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:08:57', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered 'No (N)'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-01T23:09:08', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '307b42fd-abe0-4a46-bbbe-3aa126b2b47f'	System	02 Sep 2020 04:09:12
User entered '01 Sep 2020 23:09'	System	02 Sep 2020 04:09:12

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '01 Sep 2020 17:50'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 2'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:10', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:17', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:24', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:27', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'None (0)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:32', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered 'No (N)'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-02T20:51:40', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '485c6ea1-043a-4c93-8864-1208a4966542'	System	03 Sep 2020 01:51:43
User entered '02 Sep 2020 20:51'	System	03 Sep 2020 01:51:43

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 3'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:54', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:35:58', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:05', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:10', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:13', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:19', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'None (0)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:28', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered 'No (N)'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-03T21:36:43', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '1244a9fa-0ca1-4e23-b271-45bafc878800'	System	04 Sep 2020 02:36:46
User entered '03 Sep 2020 21:36'	System	04 Sep 2020 02:36:46

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 4'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:41', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:47', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:50', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:55', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:46:57', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'None (0)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:47:01', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered 'No (N)'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-05T01:47:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fa05792b-f47b-453e-a30c-361f694c0fb5'	System	05 Sep 2020 06:47:07
User entered '05 Sep 2020 01:47'	System	05 Sep 2020 06:47:07

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 5'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:36', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:38', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:41', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:48', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:52', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'None (0)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:01:59', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered 'No (N)'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T00:02:08', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9457b96b-96c4-4fc4-a98a-abe1e8f073a1'	System	06 Sep 2020 05:02:11
User entered '06 Sep 2020 00:02'	System	06 Sep 2020 05:02:11

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 6'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:09', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:11', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:16', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:19', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'None (0)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:24', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered 'No (N)'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-06T23:37:32', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '2ee5c018-b35c-469b-bd26-fbf5f911606e'	System	07 Sep 2020 04:37:36
User entered '06 Sep 2020 23:37'	System	07 Sep 2020 04:37:36

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 7'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:07', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:10', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:12', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:15', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:22', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'None (0)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered 'No (N)'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-09-08T00:47:34', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'c2e4dde5-e7ff-48c8-92d3-07a9a1a0ddad'	System	08 Sep 2020 05:47:38
User entered '08 Sep 2020 00:47'	System	08 Sep 2020 05:47:38

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:57:08

US3922067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Lorine Cook (b) (4)	16 Sep 2020 00:19:47

US3922067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	16 Sep 2020 00:19:47

US3922067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	16 Sep 2020 00:19:47

US3922067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'This visit was not done due to subject was in hospital for confusion.' reason for change:	(b) (4)	
Data Entry Error	Lorine Cook (b) (4)	16 Sep 2020 00:36:37
User entered empty.	(b) (4)	
	Lorine Cook (b) (4)	16 Sep 2020 00:19:47
	(b) (4)	

US3922067

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 00:19:56

US3922067

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	16 Sep 2020 00:19:56

US3922067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 00:20:14

US3922067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '15 Sep 2020'	Lorine Cook (b) (4)	16 Sep 2020 00:20:14

US3922067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	Lorine Cook (b) (4)	16 Sep 2020 00:20:14

US3922067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Lorine Cook (b) (4)	16 Sep 2020 00:20:14

US3922067

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 00:20:22

US3922067

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	16 Sep 2020 00:20:22

US3922067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 20:38:15
User entered 'Yes (Y)' reason for change: Data Entry Error	System	06 Oct 2020 20:38:15
User opened query 'Data is required. Please complete.' (Site from System).	lynn yauch (b) (4)	06 Oct 2020 20:38:15
User entered empty.	(b) (4)	
	System	06 Oct 2020 20:38:06
	lynn yauch (b) (4)	06 Oct 2020 20:38:06
	(b) (4)	

US3922067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '24 Sep 2020'	lynn yauch (b) (4)	06 Oct 2020 20:38:06

US3922067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:38:06

US3922067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	06 Oct 2020 20:38:06

US3922067

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	06 Oct 2020 20:38:19

US3922067

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	06 Oct 2020 20:38:19

US3922067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please ensure to update all visit folder pages to clarify if the assessment was 'ND - not done' or 'No' where necessary. Need to update Vitals, PE, Exposure, Immuno Assessment, NP Swab folders, currently blank.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:26:04
Query 'Please ensure to update all visit folder pages to clarify if the assessment was 'ND - not done' or 'No' where necessary. Need to update Vitals, PE, Exposure, Immuno Assessment, NP Swab folders, currently blank.' answered with 'forms updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:11:42
User opened query 'Please ensure to update all visit folder pages to clarify if the assessment was 'ND - not done' or 'No' where necessary. Need to update Vitals, PE, Exposure, Immuno Assessment, NP Swab folders, currently blank.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:07:25
Query 'Please complete remaining V2 folders with applicable answer.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:06:13
User opened query 'Please complete remaining V2 folders with applicable answer.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:13:33
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:54:08

US3922067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:54:08

US3922067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:54:08

US3922067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'VISIT2'	System	30 Oct 2020 13:54:08

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Pre-Dose (PREDOSE)'	lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Post-Dose (POSTDOSE)'	lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:38

US3922067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Nov 2020 19:10:46

US3922067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:46

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

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 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'per ePIP comments, based on ongoing unresolved issues, Sub-I felt it was not in subjects best interest to receive 2nd vaccine dose.'	(b) (4) lynn yauch (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 16:23:16

US3922067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:56

US3922067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:10:56

US3922067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:10:56

US3922067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:10:56

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	lynn yauch (b) (4) (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	19 Nov 2020 19:11:09

US3922067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Query 'Please confirm if patient ever completed V2 and update all visit folders to clarify yes or no for if they were completed (exposure, NP Swab, Immuno assessment, PE, Vitals) all currently blank and data required. Thank you' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:07:31
User opened query 'Please confirm if patient ever completed V2 and update all visit folders to clarify yes or no for if they were completed (exposure, NP Swab, Immuno assessment, PE, Vitals) all currently blank and data required. Thank you' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:13:05

US3922067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '1'	System	30 Oct 2020 13:13:05

US3922067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	30 Oct 2020 13:13:14

US3922067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:13:14

US3922067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:13:14

US3922067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:14

US3922067

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:13:21

US3922067

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	30 Oct 2020 13:13:21

US3922067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	30 Oct 2020 13:13:29

US3922067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:13:29

US3922067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:29

US3922067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:29

US3922067

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Oct 2020 13:13:35

US3922067

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	30 Oct 2020 13:13:35

US3922067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	30 Oct 2020 13:13:46

US3922067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:46

US3922067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:46

US3922067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:13:46

US3922067

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Oct 2020 13:13:53

US3922067

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	30 Oct 2020 13:13:53

US3922067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Oct 2020 13:14:11

US3922067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '29 Oct 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:14:11

US3922067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Clinic (Clinic)'	lynn yauch (b) (4)	30 Oct 2020 13:14:11

US3922067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'VISIT3'	System	30 Oct 2020 13:14:11

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered empty.	System	30 Oct 2020 13:14:19

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42

US3922067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42

US3922067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	30 Oct 2020 13:14:48
User entered 'No (N)'	(b) (4) lynn yauch (b) (4)	30 Oct 2020 13:14:26
	(b) (4)	

US3922067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	System	30 Oct 2020 13:14:58
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	lynn yauch (b) (4)	30 Oct 2020 13:14:58
User entered empty.	(b) (4)	
	System	30 Oct 2020 13:14:48
	lynn yauch (b) (4)	30 Oct 2020 13:14:26
	(b) (4)	

US3922067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Oct 2020 13:16:39

US3922067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '29 Oct 2020'	lynn yauch (b) (4)	30 Oct 2020 13:16:39

US3922067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '10:36'	lynn yauch (b) (4)	30 Oct 2020 13:16:39

US3922067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered '29 Oct 2020 10:36'	System	30 Oct 2020 13:16:39

US3922067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	30 Oct 2020 13:14:31

US3922067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	30 Oct 2020 13:14:31

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 64'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-05T16:44:10', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e528e876-9acc-465f-8a1e-df0d2df99823'	System	05 Nov 2020 22:44:27
User entered 'No (N)'	System	05 Nov 2020 22:44:27

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-05T16:44:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e528e876-9acc-465f-8a1e-df0d2df99823'	System	05 Nov 2020 22:44:27
User entered 'No (N)'	System	05 Nov 2020 22:44:27

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-05T16:44:23', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'e528e876-9acc-465f-8a1e-df0d2df99823'	System	05 Nov 2020 22:44:27
User entered '05 Nov 2020 16:44:23'	System	05 Nov 2020 22:44:27

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 71'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-08T09:34:50', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7b4f198d-4ce5-41f7-8faa-1890cb5b55e4'	System	08 Nov 2020 15:35:13
User entered 'No (N)'	System	08 Nov 2020 15:35:13

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-08T09:34:55', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7b4f198d-4ce5-41f7-8faa-1890cb5b55e4'	System	08 Nov 2020 15:35:13
User entered 'No (N)'	System	08 Nov 2020 15:35:13

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-08T09:35:09', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7b4f198d-4ce5-41f7-8faa-1890cb5b55e4'	System	08 Nov 2020 15:35:13
User entered '08 Nov 2020 09:35:09'	System	08 Nov 2020 15:35:13

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:14:58
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01
Data entry locked.	System	01 Sep 2020 19:57:08
User entered 'Day 78'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 19:57:08

US3922067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:43:01
Data entry locked.	System	01 Sep 2020 19:57:08
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 19:57:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-11-29T16:02:51', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '567044eb-82e4-4a03-8d95-6dd12f74b453'	System	29 Nov 2020 22:03:08
User entered 'No (N)'	System	29 Nov 2020 22:03:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-11-29T16:02:56', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '567044eb-82e4-4a03-8d95-6dd12f74b453'	System	29 Nov 2020 22:03:08
User entered 'No (N)'	System	29 Nov 2020 22:03:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-11-29T16:03:04', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '567044eb-82e4-4a03-8d95-6dd12f74b453'	System	29 Nov 2020 22:03:08
User entered '29 Nov 2020 16:03:04'	System	29 Nov 2020 22:03:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-03T08:53:53', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd1a41b8d-e544-4991-ad69-d4b722b6fad5'	System	03 Dec 2020 14:54:05
User entered 'No (N)'	System	03 Dec 2020 14:54:05

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-12-03T08:53:57', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd1a41b8d-e544-4991-ad69-d4b722b6fad5'	System	03 Dec 2020 14:54:05
User entered 'No (N)'	System	03 Dec 2020 14:54:05

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-12-03T08:54:01', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd1a41b8d-e544-4991-ad69-d4b722b6fad5'	System	03 Dec 2020 14:54:05
User entered '03 Dec 2020 08:54:01'	System	03 Dec 2020 14:54:05

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-10T10:47:11', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc87c7cb-16d2-4e71-92bb-9598a147d747'	System	10 Dec 2020 16:47:25
User entered 'No (N)'	System	10 Dec 2020 16:47:25

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-12-10T10:47:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc87c7cb-16d2-4e71-92bb-9598a147d747'	System	10 Dec 2020 16:47:25
User entered 'No (N)'	System	10 Dec 2020 16:47:25

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-12-10T10:47:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc87c7cb-16d2-4e71-92bb-9598a147d747'	System	10 Dec 2020 16:47:25
User entered '10 Dec 2020 10:47:21'	System	10 Dec 2020 16:47:25

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-18T10:08:03', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8a2e7c5-90b5-4a65-8430-1cb2c3f2e5cb'	System	18 Dec 2020 16:08:18
User entered 'No (N)'	System	18 Dec 2020 16:08:18

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-12-18T10:08:07', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8a2e7c5-90b5-4a65-8430-1cb2c3f2e5cb'	System	18 Dec 2020 16:08:18
User entered 'No (N)'	System	18 Dec 2020 16:08:18

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-12-18T10:08:12', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8a2e7c5-90b5-4a65-8430-1cb2c3f2e5cb'	System	18 Dec 2020 16:08:18
User entered '18 Dec 2020 10:08:12'	System	18 Dec 2020 16:08:18

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-28T16:06:27', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca'	System	28 Dec 2020 22:07:13
User entered 'Yes (Y)'	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-12-28T16:06:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca'	System	28 Dec 2020 22:07:13
User entered 'No (N)'	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-28T16:06:36', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca'	System	28 Dec 2020 22:07:13
User entered 'No (N)'	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-28T16:06:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca'	System	28 Dec 2020 22:07:13
User entered 'Yes (Y)'	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Please 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 (97d76f4d492bb263)', Time: '2020-12-28T16:06:54', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca'	System	28 Dec 2020 22:07:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-12-28T16:07:01', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'cc98d5d0-179d-4299-95b2-f4c08a44c1ca' User entered '28 Dec 2020 16:07:01'	System	28 Dec 2020 22:07:13
	System	28 Dec 2020 22:07:13

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2020-12-31T00:02:03', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e1fc0c6-7ad8-48ae-8184-f5d560ed2a2e'	System	31 Dec 2020 06:02:17
User entered 'No (N)'	System	31 Dec 2020 06:02:17

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2020-12-31T00:02:06', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e1fc0c6-7ad8-48ae-8184-f5d560ed2a2e'	System	31 Dec 2020 06:02:17
User entered 'No (N)'	System	31 Dec 2020 06:02:17

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2020-12-31T00:02:14', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e1fc0c6-7ad8-48ae-8184-f5d560ed2a2e' User entered '31 Dec 2020 00:02:14'	System	31 Dec 2020 06:02:17
	System	31 Dec 2020 06:02:17

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-01-07T02:42:12', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '32cee8dc-a238-4b1b-93cf-e70edf35bf4d'	System	07 Jan 2021 08:42:24
User entered 'No (N)'	System	07 Jan 2021 08:42:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-01-07T02:42:16', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '32cee8dc-a238-4b1b-93cf-e70edf35bf4d'	System	07 Jan 2021 08:42:24
User entered 'No (N)'	System	07 Jan 2021 08:42:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-01-07T02:42:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '32cee8dc-a238-4b1b-93cf-e70edf35bf4d'	System	07 Jan 2021 08:42:24
User entered '07 Jan 2021 02:42:21'	System	07 Jan 2021 08:42:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-01-14T11:57:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '48a89416-9f49-47a5-a795-c4f48fa3df85'	System	14 Jan 2021 17:57:51
User entered 'No (N)'	System	14 Jan 2021 17:57:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-01-14T11:57:40', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '48a89416-9f49-47a5-a795-c4f48fa3df85'	System	14 Jan 2021 17:57:51
User entered 'No (N)'	System	14 Jan 2021 17:57:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-01-14T11:57:45', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '48a89416-9f49-47a5-a795-c4f48fa3df85'	System	14 Jan 2021 17:57:51
User entered '14 Jan 2021 11:57:45'	System	14 Jan 2021 17:57:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-01-21T11:54:23', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8d2df76-f7b7-4604-b269-1533d27668a4'	System	21 Jan 2021 17:54:38
User entered 'No (N)'	System	21 Jan 2021 17:54:38

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-01-21T11:54:31', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8d2df76-f7b7-4604-b269-1533d27668a4'	System	21 Jan 2021 17:54:38
User entered 'No (N)'	System	21 Jan 2021 17:54:38

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-01-21T11:54:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd8d2df76-f7b7-4604-b269-1533d27668a4'	System	21 Jan 2021 17:54:38
User entered '21 Jan 2021 11:54:35'	System	21 Jan 2021 17:54:38

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-01-30T13:30:58', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'f85dc76c-29e5-47c2-9445-70675bf89632'	System	30 Jan 2021 19:31:09
User entered 'No (N)'	System	30 Jan 2021 19:31:09

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-01-30T13:31:02', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'f85dc76c-29e5-47c2-9445-70675bf89632'	System	30 Jan 2021 19:31:09
User entered 'No (N)'	System	30 Jan 2021 19:31:09

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-01-30T13:31:05', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'f85dc76c-29e5-47c2-9445-70675bf89632'	System	30 Jan 2021 19:31:09
User entered '30 Jan 2021 13:31:05'	System	30 Jan 2021 19:31:09

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-02-04T00:56:13', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '96158098-ae89-4b6c-a19f-c84320ddfdf0'	System	04 Feb 2021 06:56:24
User entered 'No (N)'	System	04 Feb 2021 06:56:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-02-04T00:56:17', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '96158098-ae89-4b6c-a19f-c84320ddfdf0'	System	04 Feb 2021 06:56:24
User entered 'No (N)'	System	04 Feb 2021 06:56:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-04T00:56:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '96158098-ae89-4b6c-a19f-c84320ddfdf0'	System	04 Feb 2021 06:56:24
User entered '04 Feb 2021 00:56:21'	System	04 Feb 2021 06:56:24

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-02-11T00:01:22', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc88918e-30bb-49a7-9187-63e3faa5fab'	System	11 Feb 2021 06:01:49
User entered 'No (N)'	System	11 Feb 2021 06:01:49

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-02-11T00:01:25', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc88918e-30bb-49a7-9187-63e3faa5fab'	System	11 Feb 2021 06:01:49
User entered 'No (N)'	System	11 Feb 2021 06:01:49

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-11T00:01:30', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'fc88918e-30bb-49a7-9187-63e3faa5fab'	System	11 Feb 2021 06:01:49
User entered '11 Feb 2021 00:01:30'	System	11 Feb 2021 06:01:49

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-02-18T00:03:08', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '59b5da49-f29b-44d9-8218-33028f622413'	System	18 Feb 2021 06:03:22
User entered 'No (N)'	System	18 Feb 2021 06:03:22

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-02-18T00:03:12', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '59b5da49-f29b-44d9-8218-33028f622413'	System	18 Feb 2021 06:03:22
User entered 'No (N)'	System	18 Feb 2021 06:03:22

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-18T00:03:18', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '59b5da49-f29b-44d9-8218-33028f622413'	System	18 Feb 2021 06:03:22
User entered '18 Feb 2021 00:03:18'	System	18 Feb 2021 06:03:22

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-02-25T09:02:47', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '570e468e-12ea-45e3-a411-42d7018a4371'	System	25 Feb 2021 15:03:30
User entered 'No (N)'	System	25 Feb 2021 15:03:30

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-02-25T09:02:52', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '570e468e-12ea-45e3-a411-42d7018a4371'	System	25 Feb 2021 15:03:30
User entered 'No (N)'	System	25 Feb 2021 15:03:30

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-25T09:02:56', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '570e468e-12ea-45e3-a411-42d7018a4371'	System	25 Feb 2021 15:03:30
User entered '25 Feb 2021 09:02:56'	System	25 Feb 2021 15:03:30

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-03-04T00:01:21', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e1352dc-2812-4a82-825d-d16bb0937cc6'	System	04 Mar 2021 06:01:35
User entered 'No (N)'	System	04 Mar 2021 06:01:35

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-03-04T00:01:23', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e1352dc-2812-4a82-825d-d16bb0937cc6'	System	04 Mar 2021 06:01:35
User entered 'No (N)'	System	04 Mar 2021 06:01:35

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-03-04T00:01:27', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e1352dc-2812-4a82-825d-d16bb0937cc6'	System	04 Mar 2021 06:01:35
User entered '04 Mar 2021 00:01:27'	System	04 Mar 2021 06:01:35

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-03-11T11:48:43', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a86eb83f-143e-4ee5-bc51-3d36d0da9ec5'	System	11 Mar 2021 17:48:56
User entered 'No (N)'	System	11 Mar 2021 17:48:56

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-03-11T11:48:47', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a86eb83f-143e-4ee5-bc51-3d36d0da9ec5'	System	11 Mar 2021 17:48:56
User entered 'No (N)'	System	11 Mar 2021 17:48:56

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-03-11T11:48:52', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a86eb83f-143e-4ee5-bc51-3d36d0da9ec5'	System	11 Mar 2021 17:48:56
User entered '11 Mar 2021 11:48:52'	System	11 Mar 2021 17:48:56

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-03-19T09:14:03-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e2b1e30-5548-42f6-9968-0b0e51e316a5' User entered 'No (N)'	System	19 Mar 2021 14:14:12
	System	19 Mar 2021 14:14:12

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-03-19T09:14:06-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e2b1e30-5548-42f6-9968-0b0e51e316a5'	System	19 Mar 2021 14:14:12
User entered 'No (N)'	System	19 Mar 2021 14:14:12

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-03-19T09:14:09-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '7e2b1e30-5548-42f6-9968-0b0e51e316a5' User entered '19 Mar 2021 09:14:09'	System	19 Mar 2021 14:14:12
	System	19 Mar 2021 14:14:12

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-03-25T08:00:12-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a4523969-52a7-4c52-8052-cb1918b7e09a'	System	25 Mar 2021 13:00:23
User entered 'No (N)'	System	25 Mar 2021 13:00:23

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-03-25T08:00:17-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a4523969-52a7-4c52-8052-cb1918b7e09a'	System	25 Mar 2021 13:00:23
User entered 'No (N)'	System	25 Mar 2021 13:00:23

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-03-25T08:00:21-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'a4523969-52a7-4c52-8052-cb1918b7e09a'	System	25 Mar 2021 13:00:23
User entered '25 Mar 2021 08:00:21'	System	25 Mar 2021 13:00:23

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-04-01T20:31:54-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9318cb2c-489b-469c-b5fb-e3902e9a8716' User entered 'No (N)'	System	02 Apr 2021 01:32:08
	System	02 Apr 2021 01:32:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-04-01T20:31:58-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9318cb2c-489b-469c-b5fb-e3902e9a8716'	System	02 Apr 2021 01:32:08
User entered 'No (N)'	System	02 Apr 2021 01:32:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-04-01T20:32:03-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9318cb2c-489b-469c-b5fb-e3902e9a8716' User entered '01 Apr 2021 20:32:03'	System	02 Apr 2021 01:32:08
	System	02 Apr 2021 01:32:08

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-04-08T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dac5c588-7fa3-4085-9a7a-a7432d3a17bd'	System	08 Apr 2021 05:01:51
User entered 'No (N)'	System	08 Apr 2021 05:01:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-04-08T00:01:41-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dac5c588-7fa3-4085-9a7a-a7432d3a17bd'	System	08 Apr 2021 05:01:51
User entered 'No (N)'	System	08 Apr 2021 05:01:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-04-08T00:01:48-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'dac5c588-7fa3-4085-9a7a-a7432d3a17bd'	System	08 Apr 2021 05:01:51
User entered '08 Apr 2021 00:01:48'	System	08 Apr 2021 05:01:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-04-15T13:57:47-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9c271f56-255a-4717-9b4e-578de8da40a3'	System	15 Apr 2021 18:58:01
User entered 'No (N)'	System	15 Apr 2021 18:58:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-04-15T13:57:51-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9c271f56-255a-4717-9b4e-578de8da40a3'	System	15 Apr 2021 18:58:01
User entered 'No (N)'	System	15 Apr 2021 18:58:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-04-15T13:57:54-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '9c271f56-255a-4717-9b4e-578de8da40a3' User entered '15 Apr 2021 13:57:54'	System	15 Apr 2021 18:58:01
	System	15 Apr 2021 18:58:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-04-22T11:43:40-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '82509ca1-e374-4341-8acb-a8419bb3e692' User entered 'No (N)'	System	22 Apr 2021 16:43:52
	System	22 Apr 2021 16:43:52

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-04-22T11:43:43-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '82509ca1-e374-4341-8acb-a8419bb3e692'	System	22 Apr 2021 16:43:52
User entered 'No (N)'	System	22 Apr 2021 16:43:52

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-04-22T11:43:49-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '82509ca1-e374-4341-8acb-a8419bb3e692'	System	22 Apr 2021 16:43:52
User entered '22 Apr 2021 11:43:49'	System	22 Apr 2021 16:43:52

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[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 (97d76f4d492bb263)', Time: '2021-04-29T10:05:48-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e8aaae9-e79a-435b-914c-6f62d50f6c1a' User entered 'No (N)'	System	29 Apr 2021 15:18:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

Have you been exposed to someone with 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 (97d76f4d492bb263)', Time: '2021-04-29T10:05:52-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e8aaae9-e79a-435b-914c-6f62d50f6c1a'	System	29 Apr 2021 15:18:51
User entered 'No (N)'	System	29 Apr 2021 15:18:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-04-29T10:05:56-05:00', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: '0e8aaae9-e79a-435b-914c-6f62d50f6c1a' User entered '29 Apr 2021 10:05:56'	System	29 Apr 2021 15:18:51
	System	29 Apr 2021 15:18:51

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:43:01

US3922067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:43:01
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:43:01

US3922067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:22:24

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 07:15:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-28T12:16:35', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd1c9604a-21af-48c8-ac2e-f02665c77d86'	System	28 Feb 2021 18:16:57
User entered 'No (N)'	System	28 Feb 2021 18:16:57

US3922067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:22:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:15:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d76f4d492bb263)', Time: '2021-02-28T12:16:43', User OID: 'PatientReportedOutcome (US3922067)', ODM File OID: 'd1c9604a-21af-48c8-ac2e-f02665c77d86'	System	28 Feb 2021 18:16:57
User entered '28 Feb 2021 12:16:43'	System	28 Feb 2021 18:16:57

US3922067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	01 Dec 2020 18:11:39

US3922067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '25 Nov 2020'	Pamela Echols (b) (4)	01 Dec 2020 18:11:39

US3922067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	Pamela Echols (b) (4)	01 Dec 2020 18:11:39

US3922067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	01 Dec 2020 18:11:39

US3922067

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	01 Dec 2020 18:11:49

US3922067

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:42
User entered 'I'	System	01 Dec 2020 18:11:49

US3922067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Jan 2021 17:33:02

US3922067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Dec 2020'	lynn yauch (b) (4)	15 Jan 2021 17:33:02

US3922067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Jan 2021 17:33:02

US3922067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Jan 2021 17:33:02

US3922067

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Jan 2021 17:33:08

US3922067

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User entered 'I'	System	15 Jan 2021 17:33:08

US3922067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	26 Jan 2021 15:42:35

US3922067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '26 Jan 2021'	Jennifer Ruiz (b) (4)	26 Jan 2021 15:42:35

US3922067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	26 Jan 2021 15:42:35

US3922067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Jennifer Ruiz (b) (4)	26 Jan 2021 15:42:35

US3922067

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	26 Jan 2021 15:42:38

US3922067

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User entered 'I'	System	26 Jan 2021 15:42:38

US3922067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	09 Mar 2021 22:38:46
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	09 Mar 2021 18:19:42
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	09 Mar 2021 18:19:24
User entered 'No (N)'	Jennifer Ruiz (b) (4) (b) (4)	09 Mar 2021 18:19:24

US3922067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	09 Mar 2021 22:38:46
User entered empty.	Jennifer Ruiz (b) (4)	09 Mar 2021 18:19:24

US3922067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	09 Mar 2021 22:38:46
User entered empty; reason for change Data Entry Error	Jennifer Ruiz (b) (4)	09 Mar 2021 18:19:42
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Ruiz (b) (4)	09 Mar 2021 18:19:24

US3922067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	09 Mar 2021 22:38:46
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4) System	09 Mar 2021 18:19:42
Please review and reconcile.' (Site from System).		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	09 Mar 2021 18:19:24
Please review and reconcile.' (Site from System).		
User entered empty.	Jennifer Ruiz (b) (4)	09 Mar 2021 18:19:24
	(b) (4)	

US3922067

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User signature succeeded.	Michele Reynolds (b) (4)	09 Mar 2021 22:38:46
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	09 Mar 2021 18:19:48

US3922067

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:01:58
User entered 'I'	System	09 Mar 2021 18:19:48

US3922067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:49:40
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '13 Apr 2021'	Pamela Echols (b) (4)	20 Apr 2021 18:49:40
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	20 Apr 2021 18:49:40
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 18:49:40

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '13 Apr 2021'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '10:20'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 10:20'	System	20 Apr 2021 18:51:15

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '97.8' F	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Oral (Oral)'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '68'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 18:51:15

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '14'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 18:51:15

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '137'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:51:15

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '81'	Pamela Echols (b) (4)	20 Apr 2021 18:51:15
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:51:15

US3922067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	20 Apr 2021 18:51:24
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	20 Apr 2021 18:51:24
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:52:13
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '13 Apr 2021'	Pamela Echols (b) (4)	20 Apr 2021 18:52:13
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '10:30'	Pamela Echols (b) (4)	20 Apr 2021 18:52:13
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 10:30'	System	20 Apr 2021 18:52:13

US3922067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:52:25
	(b) (4)	

US3922067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:52:25

US3922067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:04:53
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	26 Apr 2021 21:53:34
	(b) (4)	

US3922067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:04:53
	(b) (4)	
User entered '26 Apr 2021'	Jennifer Ruiz (b) (4)	26 Apr 2021 21:53:34
	(b) (4)	

US3922067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:04:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	26 Apr 2021 21:53:34
	(b) (4)	

US3922067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:04:53
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	26 Apr 2021 21:53:34
	(b) (4)	

US3922067

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:04:53
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	26 Apr 2021 21:53:38
	(b) (4)	

US3922067

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 21:53:38

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:23
User closed query 'Please re enter applicable information for when contact occurred with subject in order to know that unscheduled visit needed to occur due to likely COVID19 symptoms. Please add unscheduled visit for 28Sep2020 and enter applicable PE, vitals, other assessment information.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 14:22:41
Query 'Please re enter applicable information for when contact occurred with subject in order to know that unscheduled visit needed to occur due to likely COVID19 symptoms. Please add unscheduled visit for 28Sep2020 and enter applicable PE, vitals, other assessment information.' answered with 'updated' (Site from CRA).	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:18
User entered '28 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:06
User opened query 'Please re enter applicable information for when contact occurred with subject in order to know that unscheduled visit needed to occur due to likely COVID19 symptoms. Please add unscheduled visit for 28Sep2020 and enter applicable PE, vitals, other assessment information.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 15:11:54
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:06:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 16:05:58
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:05:58
User entered '28 Sep 2020'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:38:17

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 04:47:10
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	lynn yauch (b) (4)	06 Oct 2020 21:40:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Oct 2020 21:38:17
User entered empty.	System	06 Oct 2020 21:38:17
	lynn yauch (b) (4)	06 Oct 2020 21:38:17
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:52
User entered empty.	System	06 Oct 2020 21:38:17

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:26
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:50:36
User closed query 'Please update information. ' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 14:22:46
Query 'Please update information. ' answered with 'updated' (Site from CRA).	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:24
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:06
User opened query 'Please update information. ' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 15:12:13
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:06:17
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 16:05:58
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:05:58
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:38:17

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:47
User closed query 'Please update information.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 14:22:50
Query 'Please update information.' answered with 'updated' (Site from CRA).	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:32
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	12 Oct 2020 13:46:06
User opened query 'Please update information.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 15:12:23
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:06:25
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 16:05:58
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 16:05:58
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:38:17

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: please review Days 1, 7, 9, 12, 13, 24, and 25 as it appears data is missing. If not collected please consider recording those as Not Done or update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:06:23
Query 'Per CDM: please review Days 1, 7, 9, 12, 13, 24, and 25 as it appears data is missing. If not collected please consider recording those as Not Done or update appropriately.' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	18 Jan 2021 20:20:34
User opened query 'Per CDM: please review Days 1, 7, 9, 12, 13, 24, and 25 as it appears data is missing. If not collected please consider recording those as Not Done or update appropriately.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:22:02
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	13 Oct 2020 20:18:01
Query 'Please enter applicable information (start date of suspected COVID19 symptoms). Please complete relevant fields below.	(b) (4), (b) (6)	12 Oct 2020 15:15:53
This is needed for every day that symptoms were experienced (up until negative COVID19 test received). thank you.' canceled (Site from CRA).		
Query 'Please note, 28Sep2020 will not be Day 1 but the date of subject first experiencing the COVID19 symptoms will be listed as Day 1 for the symptom log. Please update symptom log to reflect accurate start dates of symptoms. 28 Sep 2020 should be the first day of O2 saturation and temperature readings (per subject provided illness bag).' canceled (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 15:15:51
User opened query 'Please enter applicable information (start date of suspected COVID19 symptoms). Please complete relevant fields below.	(b) (4), (b) (6)	09 Oct 2020 15:13:25
This is needed for every day that symptoms were experienced (up until negative COVID19 test received). thank you.' (Site from CRA).		

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 16:03:47
User opened query 'Please note, 28Sep2020 will not be Day 1 but the date of subject first experiencing the COVID19 symptoms will be listed as Day 1 for the symptom log. Please update symptom log to reflect accurate start dates of symptoms. 28 Sep 2020 should be the first day of O2 saturation and temperature readings (per subject provided illness bag).' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:26:11
User entered 'Day 1 (Day 1)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 20:18:01
User entered '07 Sep 2020' reason for change: Data Entry Error	System	13 Oct 2020 20:18:01
User opened query 'Data is required. Please complete.' (Site from System).	Lorine Cook (b) (4)	13 Oct 2020 20:18:01
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '28 Sep 2020'	lynn yauch (b) (4)	08 Oct 2020 16:03:47
	(b) (4)	
	lynn yauch (b) (4)	08 Oct 2020 16:03:47
	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Query 'Please review answer and ensure proper selection; patient was brought into clinic for an unscheduled visit for NP swab due to possible COVID19 symptom(s) being experienced by the patient. Please answer all of the symptoms noted below per subject's information provided for COVID19 symptoms that brought patient in. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:15:58
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 16:04:57
User opened query 'Please review answer and ensure proper selection; patient was brought into clinic for an unscheduled visit for NP swab due to possible COVID19 symptom(s) being experienced by the patient. Please answer all of the symptoms noted below per subject's information provided for COVID19 symptoms that brought patient in. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:24:10
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	06 Oct 2020 21:48:48
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered '%'	System	18 Jan 2021 20:21:06
User entered empty.	System	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Lorine Cook (b) (4)	13 Oct 2020 20:18:01
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	lynn yauch (b) (4)	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:21:06
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:48:39
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:42:49

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please update date as appropriate, once you have all other prior dates entered into system for 08Sep up to 29Sep2020.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:38:48
Query 'Please update date as appropriate, once you have all other prior dates entered into system for 08Sep up to 29Sep2020.' answered with 'updated' (Site from CRA).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 20:42:27
User opened query 'Please update date as appropriate, once you have all other prior dates entered into system for 08Sep up to 29Sep2020.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 14:02:39
User entered 'Day 2 (Day 2)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:44:41

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	20 Oct 2020 18:12:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:21:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 20:21:53
User entered '29 Sep 2020' reason for change: Data Entry Error	Lorine Cook (b) (4)	13 Oct 2020 20:21:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 15:18:45
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	12 Oct 2020 15:18:45
	(b) (4)	
User entered '29 Sep 2020'	lynn yauch (b) (4)	06 Oct 2020 21:44:41
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:44:41
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please enter in data for O2 saturation, thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:38:50
Query 'Please enter in data for O2 saturation, thank you.' answered with 'assessment was not done, O2 saturation is not known' (Site from CRA).	lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:12:54
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4) (b) (4)	13 Oct 2020 20:22:40
User entered '96' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	13 Oct 2020 20:21:53
User opened query 'Please enter in data for O2 saturation, thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 15:03:28
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:44:41

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	13 Oct 2020 20:22:40
User entered '%'	System	13 Oct 2020 20:21:53
User entered empty.	System	06 Oct 2020 21:44:41

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered '97.3' F reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	13 Oct 2020 20:21:53
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	12 Oct 2020 15:18:45
User entered '97.3' F	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Moderate (Moderate)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Moderate (Moderate)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Mild (Mild)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:44:41
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:12:03
User entered 'Not Done (Not Done)'	(b) (4) lynn yauch (b) (4)	06 Oct 2020 21:44:41

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 3 (Day 3)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '09 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 4 (Day 4)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '10 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:30

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 5 (Day 5)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '11 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 6 (Day 6)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '12 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:13:59

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 7 (Day 7)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:14:41
User entered '12 Sep 2020'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:14:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:13:47
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:14:18
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:18

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 8 (Day 8)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:14:56

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 9 (Day 9)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '15 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	18 Jan 2021 20:19:37
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:07

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 10 (Day 10)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '16 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:19

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 11 (Day 11)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '17 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:31

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 12 (Day 12)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '18 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:12:05
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:15:43
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:15:43

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:43

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 13 (Day 13)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 20:12:29
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:15:55
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:15:55

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 14 (Day 14)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '20 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:08

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 15 (Day 15)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '21 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:16:22

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:16:22

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 16 (Day 16)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '22 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

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Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:24

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 17 (Day 17)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '23 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:36

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 18 (Day 18)'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '24 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:17:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User closed query 'Per CDM: Per sponsor review, please verify and update 'Symptom Days' for lines 19 thru 23.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:23:55
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:32
Query 'Per CDM: Per sponsor review, please verify and update 'Symptom Days' for lines 19 thru 23.' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4)	16 Mar 2021 12:54:44
Signature has been broken.	lynn yauch (b) (4)	16 Mar 2021 12:53:07
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 12:53:07
User opened query 'Per CDM: Per sponsor review, please verify and update 'Symptom Days' for lines 19 thru 23.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 21 (Day 21)'	lynn yauch (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '25 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:00

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:32
Signature has been broken.	lynn yauch (b) (4)	16 Mar 2021 12:53:18
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 12:53:18
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 22 (Day 22)'	lynn yauch (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '26 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (20)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:12

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:32
Signature has been broken.	lynn yauch (b) (4)	16 Mar 2021 12:53:32
User entered 'Day 21 (Day 21)' reason for change:	lynn yauch (b) (4)	16 Mar 2021 12:53:32
Data Entry Error	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 23 (Day 23)'	lynn yauch (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '27 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (21)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:26

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:32
Signature has been broken.	lynn yauch (b) (4)	16 Mar 2021 12:53:46
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 12:53:46
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Day 24 (Day 24)'	lynn yauch (b) (4)	20 Oct 2020 18:18:52

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:52

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:41:48
User entered '1'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:52

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '95' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:38:05
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:52

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered '%'	System	20 Oct 2020 18:38:05
User entered empty.	System	20 Oct 2020 18:18:52

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:38:05
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	20 Oct 2020 18:38:05
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:18:52

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:38:05
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (22)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	18 Jan 2021 19:55:16
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:18:52
	(b) (4)	

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:32
Signature has been broken.	(b) (4) lynn yauch (b) (4)	16 Mar 2021 12:53:59
User entered 'Day 23 (Day 23)' reason for change: Data Entry Error	(b) (4) lynn yauch (b) (4)	16 Mar 2021 12:53:59
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please complete all data for telemedicine visit on 29Sep2020 and capture statuses for each symptom noted, O2 saturation, etc.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:43:45
Query 'Please complete all data for telemedicine visit on 29Sep2020 and capture statuses for each symptom noted, O2 saturation, etc.' answered with '95-96%' (Site from CRA).	Chana Hines (b) (4) (b) (4)	23 Dec 2020 18:19:27
User opened query 'Please complete all data for telemedicine visit on 29Sep2020 and capture statuses for each symptom noted, O2 saturation, etc.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 21:00:45
User entered 'Day 25 (Day 25)'	lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please clarify / confirm if 30Sep2020 telemedicine visit occurred (I see the results were technically available on same day). If Investigator gave results to patient on 30Sep2020 as well, then it is possible that telemedicine visit is not required, thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:31:38
Query 'Please clarify / confirm if 30Sep2020 telemedicine visit occurred (I see the results were technically available on same day). If Investigator gave results to patient on 30Sep2020 as well, then it is possible that telemedicine visit is not required, thank you.' answered with 'subject was contacted on 30SEP2020 with negative results' (Site from CRA).	lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:43:31
User opened query 'Please clarify / confirm if 30Sep2020 telemedicine visit occurred (I see the results were technically available on same day). If Investigator gave results to patient on 30Sep2020 as well, then it is possible that telemedicine visit is not required, thank you.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 21:02:49
User entered '29 Sep 2020'	lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please enter in lowest O2 Saturation reading for that day per protocol.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:31:42
Query 'Please enter in lowest O2 Saturation reading for that day per protocol.' answered with 'subject did not report O2 reading for Day 25' (Site from CRA).	lynn yauch (b) (4) (b) (4)	18 Jan 2021 19:56:49
User opened query 'Please enter in lowest O2 Saturation reading for that day per protocol.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 23:43:34
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:38:43
User entered '95'	lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User entered empty.	System	20 Oct 2020 18:38:43
User entered '%'	System	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.2' F reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:38:43
	(b) (4)	
User entered '97.3' F	lynn yauch (b) (4)	20 Oct 2020 18:22:10
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:38:43
User entered 'Moderate (Moderate)'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:22:10
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:38:43
User entered 'Mild (Mild)'	(b) (4)	
	lynn yauch (b) (4)	20 Oct 2020 18:22:10
	(b) (4)	

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (23)

Generated On: 10 Jun 2021 10:22:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:31:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	20 Oct 2020 18:22:10

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Sep 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Nasopharyngeal Swab (Nasopharyngeallynn yauch Swab)'	(b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[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)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:24

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:02
User entered '0'	System	12 Oct 2020 14:53:46

US3922067

Folder: Covid-19 Assessment 28 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:22:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:07
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	12 Oct 2020 14:54:54

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 3 (Day 3)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 3 (Day 3)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 3 (Day 3)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 3 (Day 3)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 3 (Day 3)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 3 (Day 3)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 3 (Day 3)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 3 (Day 3)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 3 (Day 3)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:24

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 5 (Day 5)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 5 (Day 5)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 5 (Day 5)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 5 (Day 5)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 5 (Day 5)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 5 (Day 5)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 5 (Day 5)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 5 (Day 5)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 5 (Day 5)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 7 (Day 7)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 7 (Day 7)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 7 (Day 7)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 7 (Day 7)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 7 (Day 7)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 7 (Day 7)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 7 (Day 7)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 7 (Day 7)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 7 (Day 7)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 9 (Day 9)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 9 (Day 9)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 9 (Day 9)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 9 (Day 9)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 9 (Day 9)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 9 (Day 9)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 9 (Day 9)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 9 (Day 9)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 9 (Day 9)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:24

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 14 (Day 14)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 14 (Day 14)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 14 (Day 14)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 14 (Day 14)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 14 (Day 14)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 14 (Day 14)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 14 (Day 14)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 14 (Day 14)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 21 (Day 21)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 21 (Day 21)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 21 (Day 21)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 21 (Day 21)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 21 (Day 21)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 21 (Day 21)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 21 (Day 21)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 21 (Day 21)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 21 (Day 21)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:24

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User accepted default value 'Day 28 (Day 28)'	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 28 (Day 28)'	(b) (4), (b) (6)	31 Mar 2021 18:30:33
Amendment Manager: User entered 'Day 28 (Day 28)'	System	27 Mar 2021 12:34:21
Amendment Manager: User entered 'Day 28 (Day 28)'	System	06 Mar 2021 18:13:09
Amendment Manager: User entered 'Day 28 (Day 28)'	System	27 Feb 2021 18:37:30
Amendment Manager: User entered 'Day 28 (Day 28)'	System	04 Feb 2021 13:04:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
Amendment Manager: User entered 'Day 28 (Day 28)'	System	20 Jan 2021 13:38:34
Amendment Manager: User entered 'Day 28 (Day 28)'	System	30 Dec 2020 00:09:14
Amendment Manager: User entered 'Day 28 (Day 28)'	System	19 Nov 2020 21:42:47
Amendment Manager: User entered 'Day 28 (Day 28)'	System	23 Oct 2020 03:55:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 13:31:52
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	31 Mar 2021 20:19:05
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 18:30:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 17:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:08:07

US3922067

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please confirm if no saliva samples were collected (day 3 = 30Sep2020), so I can inactivate saliva collection folder if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:32:13
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 18:23:02
Query 'Please confirm if no saliva samples were collected (day 3 = 30Sep2020), so I can inactivate saliva collection folder if needed.' answered with 'saliva sample was not collected, subject negative COVID test received prior to collection of sample' (Site from CRA).	lynn yauch (b) (4) (b) (4)	18 Jan 2021 19:38:26
User opened query 'Please confirm if no saliva samples were collected (day 3 = 30Sep2020), so I can inactivate saliva collection folder if needed.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 20:58:51
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	03 Nov 2020 20:32:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 18:31:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:06:59
User closed query 'Please note that illness visit in EDC is only for patients with positive COVID19 test results from unscheduled visit. Please enter applicable information under the symptom log and the Unscheduled visit from 28Sep2020. Please clarify if subject was positive or negative for COVID19 virus - and delete data from pages if negative. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 15:06:51
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:54:21

US3922067

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Please note that illness visit in EDC is only for patients with positive COVID19 test results from unscheduled visit. Please enter applicable information under the symptom log and the Unscheduled visit from 28Sep2020. Please clarify if subject was positive or negative for COVID19 virus - and delete data from pages if negative. Thank you.' answered with 'entered in error' (Site from CRA).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:54:13
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 15:53:37
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:53:37
User opened query 'Please note that illness visit in EDC is only for patients with positive COVID19 test results from unscheduled visit. Please enter applicable information under the symptom log and the Unscheduled visit from 28Sep2020. Please clarify if subject was positive or negative for COVID19 virus - and delete data from pages if negative. Thank you.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 14:29:19
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:12:28

US3922067

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:02
User entered '28 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:32:27
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:10
	(b) (4), (b) (6)	09 Oct 2020 15:06:59
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:53:37
User entered '28 Sep 2020'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:12:28
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:02
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	03 Nov 2020 20:32:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:06:59
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:53:37
User entered 'Clinic (Clinic)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:12:28

US3922067

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered 'SICKD1'	System	03 Nov 2020 20:32:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:06:59
User entered empty.	System	08 Oct 2020 15:53:37
User entered 'SICKD1'	System	06 Oct 2020 21:12:28

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 18:31:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4)	08 Oct 2020 15:55:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 15:55:02
User entered empty; reason for change Data Entry Error	System	08 Oct 2020 15:55:02
User entered 'Yes (Y)'	lynn yauch (b) (4)	08 Oct 2020 15:55:02
	(b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '28 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '28 Sep 2020'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '09:41' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '09:41'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered '28 Sep 2020 09:41'	System	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	System	08 Oct 2020 15:55:02
User entered '28 Sep 2020 09:41'	System	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
DataPoint set to visible.	System	03 Nov 2020 20:32:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
DataPoint set to invisible.	System	08 Oct 2020 15:53:37
User entered '68.0' in	lynn yauch (b) (4)	06 Oct 2020 21:13:57
DataPoint set to visible.	(b) (4) System	06 Oct 2020 21:12:28

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
DataPoint set to visible.	System	03 Nov 2020 20:32:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
DataPoint set to invisible.	System	08 Oct 2020 15:53:37
User entered '232.2' lb	lynn yauch (b) (4)	06 Oct 2020 21:13:57
DataPoint set to visible.	(b) (4) System	06 Oct 2020 21:12:28

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '97.9' F reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '97.9' F	(b) (4)	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered 'Oral (Oral)'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '65' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '65'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered 'bpm'	System	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	System	08 Oct 2020 15:55:02
User entered 'bpm'	System	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '15' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '15'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered 'breaths/min'	System	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	System	08 Oct 2020 15:55:02
User entered 'breaths/min'	System	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '120' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '120'	(b) (4)	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered 'mmHg'	System	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	System	08 Oct 2020 15:55:02
User entered 'mmHg'	System	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:12
User entered '69' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:02
User entered '69'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:57
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User entered 'mmHg'	System	03 Nov 2020 20:33:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14
User entered empty.	System	08 Oct 2020 15:55:02
User entered 'mmHg'	System	06 Oct 2020 21:13:57

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14

US3922067

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:14

US3922067

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:19
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:32:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 18:31:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:28
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4)	08 Oct 2020 15:55:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 15:55:24
User entered empty; reason for change Data Entry Error	System	08 Oct 2020 15:55:24
User entered 'Yes (Y)'	lynn yauch (b) (4)	08 Oct 2020 15:55:24
	(b) (4)	06 Oct 2020 21:12:38

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:28
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:55:24
User entered '28 Sep 2020'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:12:38

US3922067

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:22:24

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:29
User closed query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 28SEP2020 however, there is no Illness Visit recorded. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:09:17
Query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 28SEP2020 however, there is no Illness Visit recorded. Please reconcile or clarify' answered with 'visit updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	03 Nov 2020 20:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	03 Nov 2020 20:30:33
User opened query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 28SEP2020 however, there is no Illness Visit recorded. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 18:31:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 18:31:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Oct 2020 13:59:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Oct 2020 15:07:36
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:55:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 15:55:47
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Oct 2020 15:55:47
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:13:00

US3922067

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:22:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:54
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 18:23:29
User entered '28 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 20:30:33
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Oct 2020 13:59:43
	(b) (4), (b) (6)	09 Oct 2020 15:07:36
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	08 Oct 2020 15:55:47
User entered '28 Sep 2020'	(b) (4)	
	lynn yauch (b) (4)	06 Oct 2020 21:13:00
	(b) (4)	

US3922067

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Jan 2021 20:49:29

US3922067

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 20:49:29

US3922067

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	20 Jan 2021 20:49:29

US3922067

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 20:49:29

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:11
User entered '0'	Pamela Echols (b) (4)	24 Mar 2021 16:02:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:13:11

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	Pamela Echols (b) (4)	24 Mar 2021 16:02:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:13:11

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Placebo (Placebo)'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Placebo (Placebo)'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Placebo (Placebo)'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '1'	System	20 Jan 2021 20:52:03

US3922067

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'I'	System	20 Jan 2021 20:52:03

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered empty.	System	20 Jan 2021 20:58:40
DataPoint set to visible.	System	20 Jan 2021 20:52:03

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered empty.	System	20 Jan 2021 20:58:40
DataPoint set to visible.	System	20 Jan 2021 20:52:03

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User accepted default value 'Pre-Dose (PREDOSE)'	Pamela Echols (b) (4) (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '14:00'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '19 Jan 2021 14:00'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.9' F	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Oral (Oral)'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '65'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'bpm'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '15'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'breaths/min'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '112'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '63'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered missing code ND - Not Done.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered empty.	System	20 Jan 2021 20:58:40
DataPoint set to visible.	System	20 Jan 2021 20:52:03

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User accepted default value 'Post-Dose (POSTDOSE)'	Pamela Echols (b) (4) (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '16:58'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '19 Jan 2021 16:58'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '97.4' F	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Oral (Oral)'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '77'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'bpm'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '13'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'breaths/min'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '133'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '75'	Pamela Echols (b) (4)	20 Jan 2021 20:58:40

US3922067

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	20 Jan 2021 20:58:40

US3922067

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:31
Signature has been broken.	lynn yauch (b) (4)	15 Apr 2021 15:03:17
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 15:03:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	Pamela Echols (b) (4)	20 Jan 2021 20:58:54

US3922067

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

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:31
Signature has been broken.	lynn yauch (b) (4)	15 Apr 2021 15:03:17
User entered '19 Jan 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 15:03:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 20:58:54

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 11:38:25
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered with 'updated per query' (Site from System).	lynn yauch (b) (4) (b) (4)	22 Jan 2021 13:32:25
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	20 Jan 2021 21:15:30
User entered 'Yes (Y)'	Pamela Echols (b) (4) (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mRNA-1273'	System	20 Jan 2021 21:15:30
DataPoint set to visible.	System	20 Jan 2021 20:52:03

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '16:34' reason for change: Data Entry Error	lynn yauch (b) (4)	22 Jan 2021 13:32:16
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '19 Jan 2021 16:34'	System	22 Jan 2021 13:32:16
User entered empty.	System	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'ONCE'	System	20 Jan 2021 21:15:30

US3922067

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

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 21:15:30

US3922067

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 20:18:43

US3922067

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	28 Jan 2021 20:18:43

US3922067

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '15:45'	Pamela Echols (b) (4)	28 Jan 2021 20:18:43

US3922067

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '19 Jan 2021 15:45'	System	28 Jan 2021 20:18:43

US3922067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 20:19:30

US3922067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '19 Jan 2021'	Pamela Echols (b) (4)	28 Jan 2021 20:19:30

US3922067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '15:58'	Pamela Echols (b) (4)	28 Jan 2021 20:19:30

US3922067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '19 Jan 2021 15:58'	System	28 Jan 2021 20:19:30

US3922067

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

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 20:19:40

US3922067

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

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'I'	System	28 Jan 2021 20:19:40

US3922067

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 20:21:25

US3922067

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '26 Jan 2021'	Pamela Echols (b) (4)	28 Jan 2021 20:21:25

US3922067

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Contact Made (CONTACT MADE)'	Pamela Echols (b) (4)	28 Jan 2021 20:21:25

US3922067

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	Pamela Echols (b) (4)	28 Jan 2021 20:21:25

US3922067

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	Pamela Echols (b) (4)	28 Jan 2021 20:21:34

US3922067

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'I'	System	28 Jan 2021 20:21:34

US3922067

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '1'	System	28 Jan 2021 20:21:34
DataPoint set to visible.	System	28 Jan 2021 20:21:34

US3922067

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:55:13

US3922067

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 08:37:50
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'The visit was out of window due to inclement weather. ' (Site from System).	(b) (4) Jennifer Ruiz (b) (4)	11 Mar 2021 21:55:56
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Mar 2021 21:55:13
User entered '03 Mar 2021'	Jennifer Ruiz (b) (4) (b) (4)	11 Mar 2021 21:55:13

US3922067

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Clinic (Clinic)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:55:13

US3922067

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'OLD29'	System	11 Mar 2021 21:55:13

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Ruiz (b) (4) (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '03 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '12:07'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '03 Mar 2021 12:07'	System	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '97.7' F	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Oral (Oral)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '63'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'bpm'	System	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '16'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'breaths/min'	System	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '109'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '66'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	11 Mar 2021 21:56:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Ruiz (b) (4) (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '03 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '13:13'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '03 Mar 2021 13:13'	System	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '97.9' F	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Oral (Oral)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '59'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'bpm'	System	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '13'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'breaths/min'	System	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '124'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '61'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mmHg'	System	11 Mar 2021 21:57:42

US3922067

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:14

US3922067

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '03 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:14

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'mRNA-1273'	System	11 Mar 2021 21:58:35
DataPoint set to visible.	System	28 Jan 2021 20:21:34

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '03 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '12:36'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered '03 Mar 2021 12:36'	System	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 08:38:18
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'The right arm was used due to lymph node removal from the left arm. ' (Site from System).	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:13
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	11 Mar 2021 21:58:35
User entered 'Right Arm (RIGHT ARM)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'ONCE'	System	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 21:58:35

US3922067

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:21

US3922067

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'I'	System	11 Mar 2021 21:59:21

US3922067

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:37

US3922067

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered '11 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:37

US3922067

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:37

US3922067

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:37

US3922067

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:33
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:31
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:36:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 21:59:57

US3922067

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:04:17
User entered 'I'	System	11 Mar 2021 21:59:57

US3922067

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:43:09
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '13 Apr 2021'	Pamela Echols (b) (4)	20 Apr 2021 18:43:09
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	20 Apr 2021 18:43:09
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:24

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	20 Apr 2021 18:43:09

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	20 Apr 2021 18:46:05
User entered '13 Apr 2021' reason for change: Data Entry Error	System	20 Apr 2021 18:46:05
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Pamela Echols (b) (4)	20 Apr 2021 18:46:05
User entered '13 Mar 2021'	(b) (4)	
	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '10:20'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 10:20'	System	20 Apr 2021 18:46:05
User entered '13 Mar 2021 10:20'	System	20 Apr 2021 18:45:12

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '97.8' F	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Oral (Oral)'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '68'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 18:45:12

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '14'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 18:45:12

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '137'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:45:12

US3922067

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '81'	Pamela Echols (b) (4)	20 Apr 2021 18:45:12
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:45:12

US3922067

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	20 Apr 2021 18:48:15
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '13 Apr 2021'	Pamela Echols (b) (4)	20 Apr 2021 18:48:15
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 13:04:36
	(b) (4)	
User entered '10:30'	Pamela Echols (b) (4)	20 Apr 2021 18:48:15
	(b) (4)	

US3922067

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 10:30'	System	20 Apr 2021 18:48:15

US3922067

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:22:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Query 'Please update AEs to reflect new shortness of breath noted in ePIP on Mon, 28Sep2020. Please confirm subject was brought in and started the illness visit for suspected COVID19 and not dosed for Day 29 Visit 2.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:23:32
User opened query 'Please update AEs to reflect new shortness of breath noted in ePIP on Mon, 28Sep2020. Please confirm subject was brought in and started the illness visit for suspected COVID19 and not dosed for Day 29 Visit 2.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 20:05:39
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Sep 2020 13:51:06
User entered 'No (N)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:04:31

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:38:13
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:04:47
User entered	System	10 Sep 2020 17:59:34
'USA-US212-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 17:59:34

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User coded data point as SOC: Psychiatric disorders, HLGT: Deliria (incl confusion), HLT: Confusion and disorientation, PT: Confusional state, LLT: Confusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:21:39
Data point term sent to Coder	System	09 Sep 2020 14:20:32
User entered 'Confusion'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Yes (Y)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'No (N)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'No (N)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:38:13
	(b) (4), (b) (6)	11 Sep 2020 22:37:11
User closed query 'Please review start date and clarify if should be 07Sep2020 or 08Sep2020 per note regarding confusion started 07Sep2020 in narrative. Thank you.' (Site from CRA).		
Query 'Please review start date and clarify if should be 07Sep2020 or 08Sep2020 per note regarding confusion started 07Sep2020 in narrative. Thank you.' answered with 'Start date is 07SEP2020' (Site from CRA).	Michele Reynolds (b) (4)	10 Sep 2020 21:47:29
	(b) (4)	
User entered '07 Sep 2020' reason for change: Data Entry Error	Michele Reynolds (b) (4)	10 Sep 2020 21:46:52
	(b) (4)	
User opened query 'Please review start date and clarify if should be 07Sep2020 or 08Sep2020 per note regarding confusion started 07Sep2020 in narrative. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 14:59:10
User entered '08 Sep 2020'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 21:17:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 21:17:03
User entered empty; reason for change Per Query Resolution	Michele Reynolds (b) (4) (b) (4)	13 Oct 2020 21:17:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 21:16:23
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Oct 2020 21:16:23
DataPoint Un-verified.	Michele Reynolds (b) (4) (b) (4)	13 Oct 2020 21:16:23
User entered 'UN:UN' (non-conformant).	Michele Reynolds (b) (4) (b) (4)	13 Oct 2020 21:16:23
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 15:51:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 15:51:15
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4) (b) (4)	11 Sep 2020 15:51:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 15:50:48
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 15:50:48
User entered 'Un:un' (non-conformant).	Lorine Cook (b) (4) (b) (4)	11 Sep 2020 15:50:48
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Sep 2020 21:56:54
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4) (b) (4)	10 Sep 2020 21:56:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Sep 2020 14:20:03
User entered '18:30'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:17:03
User entered '07 Sep 2020 UN:UN' (non-conformant).	System	13 Oct 2020 21:16:23
User entered empty.	System	11 Sep 2020 15:51:15
User entered '07 Sep 2020 UN:UN' (non-conformant).	System	11 Sep 2020 15:50:48
User entered empty.	System	10 Sep 2020 21:56:54
User entered '07 Sep 2020 18:30'	System	10 Sep 2020 21:46:52
User entered '08 Sep 2020 18:30'	System	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:45:15
DataPoint Un-verified.	lynn yauch (b) (4)	03 Nov 2020 18:25:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 18:25:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Yes (Y)'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:45:16
DataPoint Un-verified.	lynn yauch (b) (4)	03 Nov 2020 18:25:32
	(b) (4)	
User entered '09 Sep 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	03 Nov 2020 18:25:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered empty.	Lorine Cook (b) (4)	09 Sep 2020 14:20:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:08:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:29:32
User entered empty.	System	09 Sep 2020 14:20:03

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Yes (Y)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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) (4), (b) (6)	28 Sep 2020 15:08:36
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 '07SEP2020 SARS-CoV-2 test was NEGATIVE' (Site from Safety).	lynn yauch (b) (4) (b) (4)	25 Sep 2020 18:12:35
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)	16 Sep 2020 19:29:06
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
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).		10 Sep 2020 21:45:49
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 by data change (Site from System).		10 Sep 2020 21:45:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Sep 2020 14:20:03
User entered 'I'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '07 Sep 2020'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
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) (4), (b) (6)	14 Oct 2020 13:38:39
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 'discharge summary has been sent' (Site from Safety).	Michele Reynolds (b) (4) (b) (4)	13 Oct 2020 20:51:57
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)	16 Sep 2020 19:30:00
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '09 Sep 2020' reason for change: Data Entry Error	Michele Reynolds (b) (4) (b) (4)	10 Sep 2020 21:45:49
User entered empty.	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'No (N)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 08:28:27
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'dosing discontinued form has been completed.' (Site from DM).	lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:24:00
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 04:07:50
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:06:17
User closed query 'Please note that patient was not dosed dose #2; therefore, action taken should be updated in EDC and in AE source for subject. Patient is continuing on study, but was discontinued from treatment. Please ensure to update Endpoint for subject as treatment discontinued if not already done so. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:06:16
Query 'Please note that patient was not dosed dose #2; therefore, action taken should be updated in EDC and in AE source for subject. Patient is continuing on study, but was discontinued from treatment. Please ensure to update Endpoint for subject as treatment discontinued if not already done so. Thank you.' answered with 'vaccine second dose did not receive due to AE, Continuing on study' (Site from CRA).	Michele Reynolds (b) (4) (b) (4)	05 Nov 2020 21:51:19
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Michele Reynolds (b) (4) (b) (4)	05 Nov 2020 21:50:47
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:45:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:45:28

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Please note that patient was not dosed dose #2; therefore, action taken should be updated in EDC and in AE source for subject. Patient is continuing on study, but was discontinued from treatment. Please ensure to update Endpoint for subject as treatment discontinued if not already done so. Thank you.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:44:40
	(b) (4), (b) (6)	05 Nov 2020 15:43:29
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:39
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:38:49
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration and update accordingly.' answered with 'IP currently on hold pending results of the rest of the workup' (Site from Safety).	Michele Reynolds (b) (4)	13 Oct 2020 21:11:46
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Per Query Resolution DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 21:10:35
	lynn yauch (b) (4)	06 Oct 2020 20:55:33
User entered 'None (NONE)' reason for change: Data Entry Error	lynn yauch (b) (4)	06 Oct 2020 20:55:33
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:29:48
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03

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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	22 Apr 2021 20:10:59
	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 22:48:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 22:32:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 20:10:14
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 19:57:10
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:03:26
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'site to update Con Meds' (Site from Safety).	lynn yauch (b) (4)	06 Oct 2020 20:58:08
	(b) (4)	
DataPoint Un-verified.	lynn yauch (b) (4)	06 Oct 2020 20:54:51
	(b) (4)	
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	06 Oct 2020 20:54:51
	(b) (4)	

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None

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:29:21
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'I'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03
	(b) (4)	

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Per previous query response indicates as "updated", and Concomitant Procedure is checked, however, "Were any Concomitant Procedure performed is marked as "No". Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 12:58:08
Query 'Per CDM: Per previous query response indicates as "updated", and Concomitant Procedure is checked, however, "Were any Concomitant Procedure performed is marked as "No". Please clarify and update as appropriate.' answered with 'subject did not receive any CMs ' (Site from DM).	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:26:22
User opened query 'Per CDM: Per previous query response indicates as "updated", and Concomitant Procedure is checked, however, "Were any Concomitant Procedure performed is marked as "No". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:26:57
User closed query 'Per CDM: Other action taken is checked for 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of CONFUSION. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:26:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:39
Query 'Per CDM: Other action taken is checked for 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of CONFUSION. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 19:59:34
User entered '0' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	20 Oct 2020 19:57:10
User opened query 'Per CDM: Other action taken is checked for 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of CONFUSION. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:52:39

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	lynn yauch (b) (4)	06 Oct 2020 20:54:51
	(b) (4)	
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	06 Oct 2020 20:54:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 08:31:08
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'EDC guidelines do not specify if the procedure is Diagnostic or Medical Treatment as it only refers to "surgery/procedures" and referencing the indication. Please re-query and indicate if procedures listed should be inactivated.' (Site from DM).	lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:33:04
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 04:08:39
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is recorded therapeutic procedure that match this AE with this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 13:00:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:06:30
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is recorded therapeutic procedure that match this AE with this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' answered with 'Con procedures updated ' (Site from DM).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:24:38
User entered '1' reason for change: New Information	Michele Reynolds (b) (4)	05 Nov 2020 22:48:47
DataPoint Un-verified.	(b) (4) Michele Reynolds (b) (4)	05 Nov 2020 22:32:34

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0' reason for change: New Information	Michele Reynolds (b) (4)	05 Nov 2020 22:32:34
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is recorded therapeutic procedure that match this AE with this time frame. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:28:47
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:39
DataPoint Un-verified.	Pauline Jackson (b) (4)	20 Oct 2020 20:10:14
User entered '1' reason for change: Data Entry Error	(b) (4) Pauline Jackson (b) (4)	20 Oct 2020 20:10:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:36:02
User closed query 'PV Query: Please provide the final event outcome, when available. Per the answered query, the confusion has resolved, however per the outcome section of the AE report, the event was recovering.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:48:58
Query 'PV Query: Please provide the final event outcome, when available. Per the answered query, the confusion has resolved, however per the outcome section of the AE report, the event was recovering.' answered with 'updated ' (Site from Safety).	lynn yauch (b) (4)	03 Nov 2020 18:26:44
DataPoint Un-verified.	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	lynn yauch (b) (4)	03 Nov 2020 18:25:32
User opened query 'PV Query: Please provide the final event outcome, when available. Per the answered query, the confusion has resolved, however per the outcome section of the AE report, the event was recovering.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:37:20
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:39
User closed query 'PV Query: Please provide the final event outcome, 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)	14 Oct 2020 13:38:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Michele Reynolds (b) (4)	13 Oct 2020 21:10:35
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Awaiting results of neuro consult. Confusion has resolved but no diagnosis yet.' (Site from Safety).	Michele Reynolds (b) (4)	13 Oct 2020 21:09:11

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 19:17:11
Query 'Data is required. Please complete.' answered with 'site will updated when available' (Site from System).	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:56:45
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 20:53:49
DataPoint Un-verified.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:53:49
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:53:49
User opened query 'PV Query: Please provide the final event outcome, 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)	16 Sep 2020 19:28:25
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:38:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Narrative indicates that the subject had Unknown Tests done during hospitalization and was scheduled an EEG. However, there are no corresponding Concomitant Procedure record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 12:59:43
	(b) (4), (b) (6)	06 Nov 2020 14:06:39
User closed query 'Please have PI update narrative with additional details from received Neurologist's EEG performed. Please ensure to email the redacted medical records to the PV group email and note the subject # / SAE in the email and what you are attaching. Please file copy of the email, once sent in the subject's source.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:06:37
Query 'Please have PI update narrative with additional details from received Neurologist's EEG performed. Please ensure to email the redacted medical records to the PV group email and note the subject # / SAE in the email and what you are attaching. Please file copy of the email, once sent in the subject's source.' answered with 'Sent ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:31:43
Query 'Per DM CLR: Narrative indicates that the subject had Unknown Tests done during hospitalization and was scheduled an EEG. However, there are no corresponding Concomitant Procedure record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'Updated ' (Site from DM).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:31:36
DataPoint Un-verified.	Michele Reynolds (b) (4) (b) (4)	05 Nov 2020 21:53:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT REPORTED ON 9/8/2020 THAT SHE WAS IN HOSPITAL FOR CONFUSION THAT HAPPENED ON 9/7/2020 AROUND 18:00. WILL KNOW MORE PENDING MEDICAL RECORDS. UPDATE 10SEP2020 PATIENT REPORTED SHE WAS DISCHARGED FROM HOSPITAL ON 09SEP. NO DIAGNOSIS WAS MADE. UNKNOWN TESTS WERE DONE. PATIENT WAS TOLD BY HOSPITAL DOCTOR TO SEE HER NEUROLOGIST AND NOT TO DRIVE BECAUSE THEY THOUGHT SHE MIGHT HAVE HAD A STROKE (NOT CONFIRMED). PATIENT SAW NEUROLOGIST ON 10SEP2020. NEUROLOGIST COULD NOT ASSESS WITHOUT SEEING TEST RESULTS FROM HOSPITAL. NEUROLOGIST PLANS TO GET HOSPITAL RECORDS AND SCHEDULE 72 HOUR EEG FOR 25 OR 26SEP2020. PATIENT REPORTED SHE IS FEELING BETTER BUT TIRED AND A LITTLE "OUT OF BREATH." SHE STATED THAT SHE COULD NOT REMEMBER ABOUT 7 HOURS OF MONDAY 07SEP2020. SITE IS REQUESTING MEDICAL RECORDS. 72 hour EEG done and results were normal.' reason for change: Data Entry Error	Michele Reynolds (b) (4) (b) (4)	05 Nov 2020 21:53:36
User opened query 'Please have PI update narrative with additional details from received Neurologist's EEG performed. Please ensure to email the redacted medical records to the PV group email and note the subject # / SAE in the email and what you are attaching. Please file copy of the email, once sent in the subject's source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:52:47
Query ' Please see PV queries noted above and provide information requested via safety email and/or fax. Please ensure to file the redacted records / information with the confirmation of sent email / fax after sent to IQVIA safety team, within subject's source for SDV.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:50:40
User closed query 'PV Query: A 72-hour electroencephalogram was scheduled for 25 Sep 2020 or 26 Sep 2020. Please provide results if available.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:49:05

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was reported in the neurology consult note that the patient had evidence of UTI. Please report if this was confirmed.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:49:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:49:00
User opened query 'Per DM CLR: Narrative indicates that the subject had Unknown Tests done during hospitalization and was scheduled an EEG. However, there are no corresponding Concomitant Procedure record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:27:44
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment was provided' (Site from Safety).	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:45:31
Query 'PV Query: A 72-hour electroencephalogram was scheduled for 25 Sep 2020 or 26 Sep 2020. Please provide results if available.' answered with 'monitoring occurred 27SEP2020-29SEP2020 and impression was normal' (Site from Safety).	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:31:34
Query 'PV Query: It was reported in the neurology consult note that the patient had evidence of UTI. Please report if this was confirmed.' answered with 'subject has chronic recurrent UTI's, Med hx has been updated accordingly' (Site from Safety).	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:27:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Per the discharge summary, the subject has the following medical history: dizziness, chronic shortness of breath, chronic recurrent UTIs, and allergies to caffeine, ciprofloxacin, erythromycin, nitrofurantoin, penicillin, Septra (sulfamethoxazole and trimethoprim). Please confirm if this should be added to the subject's medical history and confirm dates.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:29:11
Query 'PV query: Per the discharge summary, the subject has the following medical history: dizziness, chronic shortness of breath, chronic recurrent UTIs, and allergies to caffeine, ciprofloxacin, erythromycin, nitrofurantoin, penicillin, Septra (sulfamethoxazole and trimethoprim). Please confirm if this should be added to the subject's medical history and confirm dates.' answered with 'Updated Med HX' (Site from Safety).	Lorine Cook (b) (4) (b) (4)	30 Oct 2020 21:06:53
User opened query 'PV Query: A 72-hour electroencephalogram was scheduled for 25 Sep 2020 or 26 Sep 2020. Please provide results if available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:21:52
User opened query ' Please see PV queries noted above and provide information requested via safety email and/or fax. Please ensure to file the redacted records / information with the confirmation of sent email / fax after sent to IQVIA safety team, within subject's source for SDV.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:59:54
Query 'Please see PV queries noted above and provide information requested via safety email and/or fax. Please ensure to file redacted records / information with confirmation of sent email / fax to safety team within subject's source. ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:59:08
User opened query 'Please see PV queries noted above and provide information requested via safety email and/or fax. Please ensure to file redacted records / information with confirmation of sent email / fax to safety team within subject's source. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:58:50

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Query 'Please update narrative to include information requested from PV queries noted below. CRA was informed today that there should not be a character limit in the narrative. Please try to add missing data in the narrative and save information in case it doesn't let you add all information. thank you. Please respond to queries after they are addressed.' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:57:48
User opened query 'Please update narrative to include information requested from PV queries noted below. CRA was informed today that there should not be a character limit in the narrative. Please try to add missing data in the narrative and save information in case it doesn't let you add all information. thank you. Please respond to queries after they are addressed.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:49:11
User opened query 'PV Query: It was reported in the neurology consult note that the patient had evidence of UTI. Please report if this was confirmed.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:39:26
User opened query 'PV query: Per the discharge summary, the subject has the following medical history: dizziness, chronic shortness of breath, chronic recurrent UTIs, and allergies to caffeine, ciprofloxacin, erythromycin, nitrofurantoin, penicillin, Septra (sulfamethoxazole and trimethoprim). Please confirm if this should be added to the subject's medical history and confirm dates.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:39:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:37:32

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EEG, ECG, neuro imaging, chest xray, UA,/urine culture, blood culture, CBC, blood chemistry, abnormal vital signs) when available. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 13:39:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EEG, ECG, neuro imaging, chest xray, UA,/urine culture, blood culture, CBC, blood chemistry, abnormal vital signs) when available. Please include units and reference ranges if applicable. ' answered with 'Chest x-ray-normal. CT scan chest-no acute changes, no evidence pulmonary embolus, CT scan head-senescent changes, no acute changes; MRI head- microvascular changes, left temporal lobe cystic changes; EEG-normal awake, drowsy and asleep	Michele Reynolds (b) (4) (b) (4)	13 Oct 2020 21:09:24
Lab: troponin 0 (normal 0-0.08); CO2 20 (normal 21-32); Chloride 110 (normal 86-108); glucose 107 (normal 70-100); pulse ox 97. results of Neurology consult and 72 hour EEG have not been received yet.' (Site from Safety).		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EEG, ECG, neuro imaging, chest xray, UA,/urine culture, blood culture, CBC, blood chemistry, abnormal vital signs) when available. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:38:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT REPORTED ON 9/8/2020 THAT SHE WAS IN HOSPITAL FOR CONFUSION THAT HAPPENED ON 9/7/2020 AROUND 18:00. WILL KNOW MORE PENDING MEDICAL RECORDS. Update 10SEP2020 Patient reported she was discharged from hospital on 09SEP. No diagnosis was made. Unknown tests were done. Patient was told by hospital doctor to see her neurologist and not to drive because they thought she might have had a stroke (not confirmed). Patient saw neurologist on 10SEP2020. Neurologist could not assess without seeing test results from hospital. Neurologist plans to get hospital records and schedule 72 hour EEG for 25 or 26SEP2020. Patient reported she is feeling better but tired and a little "out of breath." She stated that she could not remember about 7 hours of Monday 07SEP2020. Site is requesting medical records.' reason for change: Data Entry Error	Michele Reynolds (b) (4)	10 Sep 2020 22:12:02
User entered 'PT reported on 9/8/2020 that she was in hospital for confusion that happened on 9/7/2020 around 18:00. Will know more pending medical records.'	Lorine Cook (b) (4)	09 Sep 2020 14:20:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 14:20:03

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:45:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:45:25
Data point term sent to Coder	System	06 Oct 2020 20:43:44
User entered 'headache'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '28 Sep 2020'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User entered empty.	System	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '29 Sep 2020'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User entered empty.	System	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

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Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'None (NONE)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'l'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User entered '0'	System	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41
User entered '0'	System	06 Oct 2020 20:43:18

US3922067

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:51:41

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 19:48:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 19:48:11
Data point term sent to Coder	System	19 Jan 2021 19:47:20
User entered 'nausea'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '27 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User entered empty.	System	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User entered empty.	System	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User entered '0'	System	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14
User entered 'I'	System	19 Jan 2021 19:46:35

US3922067

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:14

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Jan 2021 19:50:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:50:08
Data point term sent to Coder	System	19 Jan 2021 19:49:25
User entered 'vomiting'	lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '27 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User entered empty.	System	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User entered empty.	System	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User entered '0'	System	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23
User entered '1'	System	19 Jan 2021 19:49:15

US3922067

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Recurrent urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:46:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Mar 2021 12:46:59
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	03 Mar 2021 16:19:39
Data point term sent to Coder	System	02 Mar 2021 19:15:05
Coding entries removed.	lynn yauch (b) (4) (b) (4)	02 Mar 2021 19:14:24
Signature has been broken.	lynn yauch (b) (4) (b) (4)	02 Mar 2021 19:14:24
User entered 'Worsening of chronic recurrent urinary tract infection' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	02 Mar 2021 19:14:24
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:33:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:52:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:52:09
Data point term sent to Coder	System	19 Jan 2021 19:51:26
User entered 'diarrhea'	lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '27 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User entered empty.	System	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:19:39
Signature has been broken.	lynn yauch (b) (4)	02 Mar 2021 19:14:24
User entered '04 Jan 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:14:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '28 Dec 2020'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User entered empty.	System	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'I'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '0'	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User entered '0'	System	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29
User entered 'I'	System	19 Jan 2021 19:51:03

US3922067

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:29

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:19:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 19:16:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 19:16:45
Data point term sent to Coder	System	02 Mar 2021 19:16:10
User entered 'diarrhea' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:15:18
Data point term sent to Coder	System	02 Mar 2021 18:55:39
Signature has been broken.	lynn yauch (b) (4)	02 Mar 2021 18:54:52
User entered 'WORSENING OF CHRONIC RECURRENT urinary tract infections' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 18:54:52
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
Data point term sent to Coder	System	02 Mar 2021 16:00:39
User entered 'Worsening of chronic recurrent UTIs'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '27 Dec 2020'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User entered empty.	System	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:19:39
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '28 Dec 2020' reason for change: Data Entry Error	System	02 Mar 2021 19:15:33
User opened query 'Future date has been entered. Please correct.' (Site from System).	lynn yauch (b) (4)	02 Mar 2021 19:15:33
Signature has been broken.	(b) (4)	
User entered '28 Dec 2021' reason for change: Data Entry Error	System	02 Mar 2021 19:15:18
User signature succeeded.	lynn yauch (b) (4)	02 Mar 2021 19:15:18
User entered '04 Jan 2021'	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:15:18
	(b) (4)	
	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
	Chana Hines (b) (4)	02 Mar 2021 16:00:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User entered empty.	System	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 16:01:35
User entered 'No (N)' reason for change: Per Query Resolution	System	02 Mar 2021 16:01:35
User opened query 'Data is required. Please complete.' (Site from System).	Chana Hines (b) (4)	02 Mar 2021 16:01:35
User entered empty.	(b) (4)	
	System	02 Mar 2021 16:00:27
	Chana Hines (b) (4)	02 Mar 2021 16:00:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	02 Mar 2021 16:01:35
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	02 Mar 2021 16:01:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Mar 2021 16:00:27
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty; reason for change Data Entry Error	Chana Hines (b) (4)	02 Mar 2021 16:01:35
User entered 'No (N)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Not Related (NOT RELATED)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Not Related (NOT RELATED)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Not Applicable (NOT APPLICABLE)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'I'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	Chana Hines (b) (4)	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User entered '0'	System	02 Mar 2021 16:01:35

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User entered 'I'	System	02 Mar 2021 16:00:27

US3922067

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:22:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:39
User entered '0'	System	02 Mar 2021 16:00:27

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Lid, lash and lacrimal structural disorders, PT: Dacryostenosis acquired, LLT: Dacryostenosis acquired - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 21:05:59
Data point term sent to Coder	(b) (4)	
User entered 'Dacryostenosis'	System	22 Apr 2021 21:05:22
	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'No (N)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'No (N)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '01 Feb 2021'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 21:05:08

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Folder: Adverse Events

Form: Adverse Events (8)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 21:05:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'No (N)'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

US3922067

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

US3922067

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

US3922067

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 21:05:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:08
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 21:05:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:08
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 21:05:31
User entered 'None (NONE)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 21:05:08
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered 'I'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08

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Folder: Adverse Events

Form: Adverse Events (8)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:38
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	22 Apr 2021 21:05:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 21:05:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:22:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 21:05:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:22:24

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:15:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 21:26:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:26:34
User closed query 'Please update con meds as necessary based on response to PV query for Confusion SAE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:26:31
Query 'Please update con meds as necessary based on Pauline Jackson response to PV query for Confusion SAE. Thank you.' answered with 'no medication taken for confusion' (Site from CRA).	(b) (4)	20 Oct 2020 20:01:48
User opened query 'Please update con meds as necessary based on response to PV query for Confusion SAE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 14:06:31
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:04:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:06:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:06:42
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 20:05:57
User entered 'synthroid'	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR-RQ: Response noted as MH updated, however, please note that there is a record of Hyperthyroidism(MH#1) and no mention of Hypothyroidism in MH eCRF. Please kindly review and reconcile if the indication is for Hyperthyroidism or Hypothyroidism.and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 09:57:44
Query 'Per DM CLR-RQ: Response noted as MH updated, however, please note that there is a record of Hyperthyroidism(MH#1) and no mention of Hypothyroidism in MH eCRF. Please kindly review and reconcile if the indication is for Hyperthyroidism or Hypothyroidism.and update accordingly. Thank you.' answered with 'MH has been updated per source to "hypothyroidism"' (Site from DM).	lynn yauch (b) (4) (b) (4)	24 Nov 2020 20:38:32
User opened query 'Per DM CLR-RQ: Response noted as MH updated, however, please note that there is a record of Hyperthyroidism(MH#1) and no mention of Hypothyroidism in MH eCRF. Please kindly review and reconcile if the indication is for Hyperthyroidism or Hypothyroidism.and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 15:02:12
User closed query 'Per DM CLR: Please note that this condition 'HYPOTHYROIDISM' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition (HYPOTHYROIDISM) and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 14:57:16
Query 'Per DM CLR: Please note that this condition 'HYPOTHYROIDISM' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition (HYPOTHYROIDISM) and all applicable details to the appropriate MH eCRF. ' answered with 'MH updated ' (Site from DM).	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 16:49:21
User opened query 'Per DM CLR: Please note that this condition 'HYPOTHYROIDISM' is not recorded on the MH eCRF. Please review Con Med use and add a medical condition (HYPOTHYROIDISM) and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:02:01

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'hypothyroidism'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '50'	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Un-verified.	(b) (4)	
	Pauline Jackson (b) (4)	11 Nov 2020 21:09:10
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	11 Nov 2020 21:09:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Other (OTHER)'	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per CDM: if dose unit is other, specify is recorded "MICROGRAMS". However "ug" dose unit is available in drop down in Dose unite. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 09:23:14
Query 'Per CDM: if dose unit is other, specify is recorded "MICROGRAMS". However "ug" dose unit is available in drop down in Dose unite. Please update accordingly. Thank you.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:09:18
DataPoint Un-verified.	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:09:10
User entered empty; reason for change Data Entry Error	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:09:10
User opened query 'Per CDM: if dose unit is other, specify is recorded "MICROGRAMS". However "ug" dose unit is available in drop down in Dose unite. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:21:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'micrograms'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:05:47
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:05:47

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:07:46
Data point term sent to Coder	System	04 Sep 2020 20:06:58
User entered 'atorvastatin'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'hypercholesterolemia'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '40'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'twice daily (BID)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2015'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:06:23
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:06:23

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 15:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 15:07:42
Data point term sent to Coder	System	02 Mar 2021 15:06:26
Coding entries removed.	Chana Hines (b) (4) (b) (4)	02 Mar 2021 15:06:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:08:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:08:51
Data point term sent to Coder	System	04 Sep 2020 20:07:59
User entered 'eliquis'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
DataPoint Un-verified.	Chana Hines (b) (4)	02 Mar 2021 15:06:15
	(b) (4)	
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Chana Hines (b) (4)	02 Mar 2021 15:06:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'atrial fibrillation'	Cristina Puig (b) (4)	04 Sep 2020 20:07:09
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '5'	Cristina Puig (b) (4)	04 Sep 2020 20:07:09
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'twice daily (BID)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2015'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:07:09
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:07:09
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:07:09

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	12 Jan 2021 15:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:08:54
Data point term sent to Coder	System	11 Jan 2021 22:02:58
Coding entries removed.	Chana Hines (b) (4) (b) (4)	11 Jan 2021 22:02:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:13:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:13:12
Data point term sent to Coder	System	17 Nov 2020 16:51:53
Coding entries removed.	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 16:50:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:30:46

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'dymista (azclastine/fluticsone)'	Coder Import (b) (4) (b) (4) System Cristina Puig (b) (4) (b) (4)	05 Sep 2020 05:30:46 04 Sep 2020 20:09:00 04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 15:03:35
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' answered with 'updated ' (Site from DM).	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 16:51:03
DataPoint Un-verified.	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 16:50:56
User entered 'CHRONIC ALLERGIES (Chemical)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	17 Nov 2020 16:50:56
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:03:49
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'chronic allergies'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '137/50'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 15:03:39
DataPoint Un-verified.	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:10:41
User entered 'ug (ug)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:10:35
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:04:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Other (OTHER)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
DataPoint Un-verified.	Pauline Jackson (b) (4)	11 Nov 2020 21:10:35
	(b) (4)	
User entered empty; reason for change Data Entry Error	Pauline Jackson (b) (4)	11 Nov 2020 21:10:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'micrograms'	Cristina Puig (b) (4)	04 Sep 2020 20:08:21
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
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) (4), (b) (6)	12 Jan 2021 13:08:35
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 per query' (Site from DM).	Chana Hines (b) (4) (b) (4)	11 Jan 2021 22:02:58
DataPoint Un-verified.	Chana Hines (b) (4) (b) (4)	11 Jan 2021 22:02:33
User entered 'Nasal (NASAL)' reason for change: Per Query Resolution	Chana Hines (b) (4) (b) (4)	11 Jan 2021 22:02:33
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)	11 Jan 2021 15:37:49
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2017'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:08:21
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:08:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:09:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:09:20
Data point term sent to Coder User entered 'vitamin D3'	System lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:31 06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 06:30:35
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated as prophylaxis in source.' (Site from DM).	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:49:56
DataPoint Un-verified.	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:49:51
User entered 'Yes (Y)' reason for change: Per Query Resolution	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:49:51
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 01:57:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'supplement'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '2000'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
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) (4), (b) (6)	18 Dec 2020 09:17:00
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 'Contacted subject on 12/17/2020. Subject verified Kirkland brand. Dosing unit is IU.' (Site from DM).	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:45:39
DataPoint Un-verified.	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:45:35
User entered 'IU (IU)' reason for change: New Information	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:45:35
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)	02 Dec 2020 02:58:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:07:33

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:09:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:09:21
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 21:08:32
User entered 'omega 3'	lynn yauch (b) (4)	06 Oct 2020 21:08:04
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'supplement'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'I'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'tablet (TABLET)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:08:04

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: FALLOPIA JAPONICA;VITIS VINIFERA SEED, PRODUCTSYNONYM: RESVERATROL & GRAPESEED EXTRACT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 21:18:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:18:48
Data point term sent to Coder DataPoint Un-verified.	System Chana Hines (b) (4)	17 Dec 2020 21:16:55 17 Dec 2020 21:15:55
Coding entries removed.	Chana Hines (b) (4) (b) (4)	17 Dec 2020 21:15:55
User entered 'GRAPESEED EXTRACT with Resveratrol' reason for change: Data Entry Error	Chana Hines (b) (4) (b) (4)	17 Dec 2020 21:15:55
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VITIS VINIFERA EXTRACT, PRODUCTSYNONYM: GRAPESEED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:16:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:16:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
Data point term sent to Coder	System	06 Oct 2020 21:09:35
User entered 'grapeseed extract'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 06:31:31
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated as prophylaxis in source.' (Site from DM).	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:50:59
DataPoint Un-verified.	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:50:18
User entered 'Yes (Y)' reason for change: Per Query Resolution	Chana Hines (b) (4) (b) (4)	12 Feb 2021 22:50:18
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 01:58:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'supplement'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per DM CLR RQ: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/15).' (Site from DM). Query 'Per DM CLR RQ: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/15).' answered with 'Per source documentation, supplement contains 12/5mg Grapeseed Extract / 15mg Resveratrol.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 06:31:37
User entered '12.5mg/15mg' reason for change: Per Query Resolution	Chana Hines (b) (4) (b) (4)	12 Feb 2021 23:03:48
User entered '12.5 Grapeseed Extract' reason for change: New Information	Chana Hines (b) (4) (b) (4)	12 Feb 2021 23:02:14
User opened query 'Per DM CLR RQ: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/15).' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 01:58:55
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:16:47
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with '12.5mg grapeseed extract 15mg resveratrol' (Site from DM).	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:44:30
DataPoint Un-verified.	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:44:06
User entered '12.5' reason for change: New Information	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:44:06

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 02:57:44
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '15'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:08:37

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:11:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:11:23
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 21:10:37
User entered 'COQ10'	lynn yauch (b) (4)	06 Oct 2020 21:09:45
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'supplement'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '200'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:09:45

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VACCINIUM MACROCARPON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:11:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:11:24
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 21:10:40
User entered 'cranberry'	lynn yauch (b) (4)	06 Oct 2020 21:10:12
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'supplement'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '300'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mg (mg)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Oral (ORAL)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'un UNK 2010'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:10:12

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 09:01:07
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'Verified subject's flu vaccine was administered on 14SEP2020. Noted protocol deviation.' (Site from DM).	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:22:25
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:08:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:06:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:22
Data point term sent to Coder	System	03 Nov 2020 18:20:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'flu vaccine'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'flu prophylaxis'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0.5'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'mL (mL)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'once (ONCE)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'Intramuscular (INTRAMUSCULAR)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered empty.	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '14 Sep 2020'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '0'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered '14 Sep 2020'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:06:07
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered empty.	System	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered empty.	System	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered empty.	System	03 Nov 2020 18:19:50

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:39
Data point term sent to Coder	System	16 Mar 2021 12:30:55
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	02 Mar 2021 18:27:18
Data point term sent to Coder	System	02 Mar 2021 15:18:46
Coding entries removed.	Chana Hines (b) (4) (b) (4)	02 Mar 2021 15:18:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:30:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:30:09
Data point term sent to Coder	System	18 Jan 2021 18:44:35
User entered 'macrobid'	lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	16 Mar 2021 12:30:50
User entered 'AE#6 Worsening CHRONIC RECURRENT URINARY TRACT INFECTIONS'	(b) (4)	
reason for change: Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 12:30:50
User signature succeeded.	(b) (4)	
	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'AE6 CHRONIC RECURRENT URINARY TRACT INFECTIONS' reason for change: Data Entry Error	(b) (4)	
	Chana Hines (b) (4)	02 Mar 2021 15:18:22
	(b) (4)	
User entered 'Chronic Recurrent Urinary Tract Infections'	lynn yauch (b) (4)	18 Jan 2021 18:43:35
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '100'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'mg (mg)'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'twice daily (BID)'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
User closed query 'per DM CLR: RQ: Response noted. However, please consider updating indication to match corresponding AE. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:25:36
Query 'per DM CLR: RQ: Response noted. However, please consider updating indication to match corresponding AE. Thank you.' answered with 'updated per source.' (Site from DM).	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:53:58
Signature has been broken.	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:53:05
User entered '27 Dec 2020' reason for change: New Information	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:53:05
User opened query 'per DM CLR: RQ: Response noted. However, please consider updating indication to match corresponding AE. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:21:04
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC RECURRENT URINARY TRACT INFECTIONS should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:21:04
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	02 Mar 2021 18:27:18
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC RECURRENT URINARY TRACT INFECTIONS should be recorded, and update con med indication or provide clarification.' answered with 'Per MR, CM11 given for AE6 (worsening of chronic recurrent UTIs).' (Site from DM).	Chana Hines (b) (4) (b) (4)	02 Mar 2021 15:15:42

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC RECURRENT URINARY TRACT INFECTIONS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:41:40
User entered '28 Dec 2020' reason for change: New Information	Chana Hines (b) (4)	12 Feb 2021 23:29:09
User entered '27 Dec 2020'	lynn yauch (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Chana Hines (b) (4)	02 Mar 2021 15:18:22
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '05 Jan 2021' reason for change: Per Query Resolution	(b) (4) Chana Hines (b) (4)	02 Mar 2021 15:18:22
User entered empty.	(b) (4) lynn yauch (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 11:25:39
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated per source.' (Site from DM).	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:57:56
Signature has been broken.	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:56:25
User entered 'No (N)' reason for change: Per Query Resolution	Pamela Echols (b) (4) (b) (4)	24 Mar 2021 15:56:25
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:58:26
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	02 Mar 2021 18:27:18
User entered 'Yes (Y)' reason for change: Per Query Resolution	Chana Hines (b) (4) (b) (4)	02 Mar 2021 15:18:22
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User entered '2'	System	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User entered '1'	System	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:38
User entered '804 (804)'	System	18 Jan 2021 18:43:35

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ZOFTRAN [ONDANSETRON HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:04:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:04:36
Data point term sent to Coder	System	02 Mar 2021 19:07:59
Signature has been broken.	lynn yauch (b) (4)	02 Mar 2021 19:07:29
User entered 'ONDANSETRON HCL/ZOFTRAN' reason for change: New Information	lynn yauch (b) (4)	02 Mar 2021 19:07:29
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
Data point term sent to Coder	System	02 Mar 2021 15:23:51
Coding entries removed.	Chana Hines (b) (4)	02 Mar 2021 15:23:11
Coding entries removed.	Chana Hines (b) (4)	02 Mar 2021 15:23:11
User entered 'ONDANSETRON HCL/ZOFTRAN IV' reason for change: New Information	Chana Hines (b) (4)	02 Mar 2021 15:23:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ZOFTRAN [ONDANSETRON HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 12:02:40
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 12:02:40
Data point term sent to Coder	System	12 Feb 2021 23:09:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Chana Hines (b) (4)	12 Feb 2021 23:08:41
User entered 'ZOFRAN HCL' reason for change: Data Entry Error	Chana Hines (b) (4)	12 Feb 2021 23:08:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:34:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:34:01
Data point term sent to Coder	System	19 Jan 2021 19:57:41
User entered 'zofran'	lynn yauch (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'NAUSEA/VOMITING (AE 4/5)'	(b) (4)	
reason for change: Data Entry Error	Chana Hines (b) (4)	02 Mar 2021 15:23:11
User entered 'nausea/vomiting(AE 4/5)'	(b) (4)	
	lynn yauch (b) (4)	19 Jan 2021 19:57:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:06:24
	(b) (4)	
User entered '8' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:06:24
	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:24:23
Query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with 'Per medical records, date of ER visit and dosing updated per query resolution' (Site from DM).	Chana Hines (b) (4)	12 Feb 2021 23:09:17
	(b) (4)	
User entered '8mg' reason for change: Data Entry Error	Chana Hines (b) (4)	12 Feb 2021 23:08:41
	(b) (4)	
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:38:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 08:38:22
Query 'Data is required. Please complete.' answered with 'amount is unknown pending medical records' (Site from System).	lynn yauch (b) (4)	19 Jan 2021 19:57:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 19:57:21
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 19:57:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:06:24
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:06:24
User signature succeeded.	(b) (4)	
	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User entered 'mL (mL)'	lynn yauch (b) (4)	19 Jan 2021 19:57:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'once (ONCE)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '28 Dec 2020' reason for change: Per Query Resolution	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:08:41
User entered '27 Dec 2020'	(b) (4) lynn yauch (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '28 Dec 2020' reason for change: Per Query Resolution	(b) (4)	
	Chana Hines (b) (4)	12 Feb 2021 23:08:41
User entered '27 Dec 2020'	(b) (4)	
	lynn yauch (b) (4)	19 Jan 2021 19:57:21
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michele Reynolds (b) (4)	02 Apr 2021 06:16:01 01 Apr 2021 16:19:09
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated per query' (Site from DM). Signature has been broken.	lynn yauch (b) (4) lynn yauch (b) (4)	01 Apr 2021 13:45:27 01 Apr 2021 13:44:41
User entered 'No (N)' reason for change: New Information	lynn yauch (b) (4)	01 Apr 2021 13:44:41
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michele Reynolds (b) (4)	16 Mar 2021 12:58:33 02 Mar 2021 18:27:18
User entered 'Yes (Y)' reason for change: New Information	Chana Hines (b) (4)	02 Mar 2021 15:23:11
User entered 'No (N)'	lynn yauch (b) (4)	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User entered empty.	System	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User entered empty.	System	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:43
User entered empty.	System	19 Jan 2021 19:57:21

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User closed query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the IV HYDRATION or provide the Trade name if known, as there are various IV HYDRATION medications available. Please update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:16:11
Query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the IV HYDRATION or provide the Trade name if known, as there are various IV HYDRATION medications available. Please update as appropriate. Otherwise, clarify.' answered with 'pending additional records requested for medications received in ER' (Site from DM).	lynn yauch (b) (4) (b) (4)	01 Apr 2021 13:42:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:15:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:15:45
User opened query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the IV HYDRATION or provide the Trade name if known, as there are various IV HYDRATION medications available. Please update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:02:46
Data point term sent to Coder	System	02 Mar 2021 19:12:01
Coding entries removed.	lynn yauch (b) (4) (b) (4)	02 Mar 2021 19:11:34
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	02 Mar 2021 18:27:18

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
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: GLUCOSE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE, PRODUCTSYNONYM: ORAL REHYDRATION SALT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:17:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 00:17:11
Data point term sent to Coder	System	19 Jan 2021 20:00:43
User entered 'TV hydration'	lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'nausea/vomiting/diarrhea(AE 4,5,6)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:04:58
	(b) (4)	
User entered '300' reason for change: New Information	lynn yauch (b) (4)	02 Mar 2021 19:04:58
	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:25:30
Query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' answered with '300ml 0.9% NS per medical records and are now in source.' (Site from DM).	Chana Hines (b) (4)	12 Feb 2021 23:07:18
	(b) (4)	
User entered '300ml 0.9% NS' reason for change: New Information	Chana Hines (b) (4)	12 Feb 2021 23:06:18
	(b) (4)	
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'pending medical records'. However, request you please keep this query open until site get reports and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:38:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 08:38:37
Query 'Data is required. Please complete.' answered with 'dose unknown, pending medical records' (Site from System).	lynn yauch (b) (4)	19 Jan 2021 20:00:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 20:00:16
User entered empty.	lynn yauch (b) (4)	19 Jan 2021 20:00:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'mL (mL)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
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).	(b) (4)	
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	12 Feb 2021 23:09:52
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	12 Feb 2021 23:09:52
User entered 'once (ONCE)'	System	12 Feb 2021 23:09:37
	lynn yauch (b) (4)	19 Jan 2021 20:00:16
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:11:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:11:34
User signature succeeded.	(b) (4)	
	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	lynn yauch (b) (4)	19 Jan 2021 20:00:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '28 Dec 2020' reason for change: New Information	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:09:37
User entered '27 Dec 2020'	(b) (4) lynn yauch (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User entered '28 Dec 2020' reason for change: New Information	System	12 Feb 2021 23:09:52
User opened query 'End date is prior to start date. Please correct.' (Site from System).	Chana Hines (b) (4)	12 Feb 2021 23:09:52
User entered '27 Dec 2020'	(b) (4)	
	System	12 Feb 2021 23:09:37
	lynn yauch (b) (4)	19 Jan 2021 20:00:16
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	19 Jan 2021 20:00:16

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
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, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:23:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:23:44
Data point term sent to Coder Coding entries removed.	System lynn yauch (b) (4)	16 Mar 2021 12:29:53 16 Mar 2021 12:28:56
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, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:03
Data point term sent to Coder Signature has been broken.	System lynn yauch (b) (4)	02 Mar 2021 19:12:01 02 Mar 2021 19:11:18
User entered 'ROCEPHIN (CEFTRIAXONE)' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:11:18
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
Data point term sent to Coder	System	12 Feb 2021 23:17:38
User entered 'Rocephin (Ceftriaxone) IV / 10ml NS - 3-5min slow IV push'	Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
User entered 'AE#6 WORSENING OF CHRONIC RECURRENT URINARY TRACT INFECTIONS'	(b) (4)	
reason for change: Data Entry Error	lynn yauch (b) (4)	16 Mar 2021 12:28:56
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:11:18
	(b) (4)	
User entered 'AE#6 worsen of chronic recurrent urinary tract infections' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:11:18
	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User entered 'UTI'	Chana Hines (b) (4)	12 Feb 2021 23:17:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'I'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'g (g)'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'once (ONCE)'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
Signature has been broken.	(b) (4)	
	lynn yauch (b) (4)	02 Mar 2021 19:11:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	lynn yauch (b) (4)	02 Mar 2021 19:11:18
User signature succeeded.	(b) (4)	
	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Chana Hines (b) (4)	12 Feb 2021 23:17:11
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered empty.	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '28 Dec 2020'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '0'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
User entered '28 Dec 2020'	(b) (4) Chana Hines (b) (4)	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User signature succeeded.	Michele Reynolds (b) (4)	01 Apr 2021 16:19:09
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 09:21:08
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'data entry error' (Site from DM).	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:29:11
Signature has been broken.	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:28:36
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:28:36
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 10:02:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 18:27:18
	(b) (4)	
User entered 'Yes (Y)'	Chana Hines (b) (4)	12 Feb 2021 23:17:11
	(b) (4)	

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User entered empty.	System	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User entered empty.	System	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:53
User entered empty.	System	12 Feb 2021 23:17:11

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:22:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Please review subject's chart and ensure to include the procedures performed at the hospital and at the Neurologist for patient as applicable (in attempts to diagnose SAE 'Confusion'). Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:18:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:18:25
Query 'Please review subject's chart and ensure to include the procedures performed at the hospital and at the Neurologist for patient as applicable (in attempts to diagnose SAE 'Confusion'). Thank you.' answered with 'Done' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:33:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 22:59:42
User opened query 'Please review subject's chart and ensure to include the procedures performed at the hospital and at the Neurologist for patient as applicable (in attempts to diagnose SAE 'Confusion'). Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:38:48
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:04:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '09 Sep 2020'	Lorine Cook (b) (4)	05 Nov 2020 23:15:37
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Echocardiogram'	Lorine Cook (b) (4)	05 Nov 2020 23:15:37
	(b) (4)	

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Query 'Please clarify if there is an SAE option or if this is correct as is. Thank you.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:26:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:19:16
User opened query 'Please clarify if there is an SAE option or if this is correct as is. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:19:13
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:15:37

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:15:37

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '07 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:17

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'CT Chest'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:17

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:17

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:17

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '07 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:46

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'CT scan of Head'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:46

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:46

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:36
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:16:46

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '27 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:17:42

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'EEG(72 hours)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:17:42

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 09:02:08
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'Corresponding medical condition is AE#1 (confusion). Subject had unexplained confusion, shortness of breath, and loss of consciousness. EEG was appropriate per PI.' (Site from DM).	Chana Hines (b) (4) (b) (4)	17 Dec 2020 20:00:14
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:24:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:17:42

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:17:42

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:43
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '08 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:19

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:43
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'MRI Head'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:19

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:43
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:19

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:43
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:19

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:48
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '08 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:45

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:48
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'EEG'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:45

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:48
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:45

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:48
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:18:45

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:22:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered '08 Sep 2020'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:22:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:22:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'EEG'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:22:55

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:22:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered 'Adverse Event (AE)'	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:22:55

US3922067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:22:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:12:52
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:20:55
User entered empty.	Lorine Cook (b) (4) (b) (4)	05 Nov 2020 23:22:55

US3922067

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:22:24

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:59:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered '29 Oct 2020'	lynn yauch (b) (4)	15 Jan 2021 16:40:01

US3922067

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:22:24

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:59:40
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
User entered 'SAE (specify) (SAE)'	lynn yauch (b) (4)	15 Jan 2021 16:40:01

US3922067

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:22:24

If reason is AE, SAE, 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 05:59:40
User signature succeeded.	Michele Reynolds (b) (4)	17 Mar 2021 13:01:22
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 07:23:02
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:40:53
Signature has been broken.	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:40:45
User entered 'SAE #1' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Mar 2021 12:40:45
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. SAE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:25:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:33:43
User closed query 'Per CDM: Per CCG V3.0 Page 49. If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:01:42
Query 'Per CDM: Per CCG V3.0 Page 49, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	22 Jan 2021 13:31:23
User entered 'Confusion(SAE #1)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	22 Jan 2021 13:31:15

US3922067

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:22:24

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG V3.0 Page 49, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM). User entered 'subject did not receive 2nd dose due to SAE for confusion'	(b) (4), (b) (6)	21 Jan 2021 08:28:12
	lynn yauch (b) (4)	15 Jan 2021 16:40:01

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered		
'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
User entered '10/Sep/2020 14:05'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered		
'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
User entered '11/Sep/2020 08:59'	System	11 Sep 2020 12:59:01

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 12:59:01

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
User entered '11/Sep/2020 11:59'	System	11 Sep 2020 15:59:25

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:08:52
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 15:59:25

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
User entered '28/Sep/2020 11:09'	System	28 Sep 2020 15:09:02

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 15:09:02

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
User entered '07/Oct/2020 09:28'	System	07 Oct 2020 13:28:41

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 13:28:41

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered		
'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
User entered '14/Oct/2020 09:39'	System	14 Oct 2020 13:39:19

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 13:39:19

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:06
User entered '21/Oct/2020 18:05'	System	21 Oct 2020 18:05:47

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 22:10:01
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:05:47

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:05:38
User entered '02/Nov/2020 20:40'	System	03 Nov 2020 01:40:08

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:05:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 13:49:38
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 01:40:08

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered		
'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	(b) (4)	
	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39
	(b) (4)	

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:05:38
User entered '04/Nov/2020 08:49'	System	04 Nov 2020 13:49:48

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:22:24

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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:12:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:05:38
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 13:49:48

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'USA-US212-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

US3922067

Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'Yes (Y)'	System	10 Sep 2020 17:59:34

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 18:05:05
User entered 'No (N)'	System	10 Sep 2020 17:59:34

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Michele' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Jennifer'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Michele'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Reynolds' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'Bashour'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Reynolds'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

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Generated On: 10 Jun 2021 10:22:24

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '9 Medical Pkwy Suite 202' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '9 Medical Pkwy. Plaza 4 Suite 202' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '7515 Greenville Ave'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'Dallas' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered 'Dallas'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:24

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered 'TX' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:39:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Un-verified.	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Jan 2021 21:05:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:05:30
Un-reviewed for Safety.	System	14 Oct 2020 13:39:19
User entered empty.	System	14 Oct 2020 13:39:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:39:10
Un-reviewed for Safety.	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
User entered '75234' reason for change: Data Entry Error	Michele Reynolds (b) (4)	13 Oct 2020 20:50:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered empty.	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
User entered '75234' reason for change: Data Entry Error	lynn yauch (b) (4)	17 Sep 2020 14:27:21
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:56:35
Amendment Manager: DataPoint Un-verified.	System	14 Sep 2020 21:56:35
Amendment Manager: User entered '75231'	System	14 Sep 2020 21:56:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty.	Cristina Puig (b) (4)	10 Sep 2020 19:11:39

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:18:06
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:28:31
Un-reviewed for Safety.	System	28 Sep 2020 15:09:02
User entered 'US'	System	28 Sep 2020 15:09:02
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 15:08:52
Un-reviewed for Safety.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Un-verified.	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	11 Sep 2020 23:08:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 22:36:45
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:58:47
Un-reviewed for Safety.	System	11 Sep 2020 12:59:01
User entered 'US' (non-conformant).	System	11 Sep 2020 12:59:01
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 12:58:24
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	10 Sep 2020 19:15:32
	(b) (4)	
User entered 'US' (non-conformant).	System	10 Sep 2020 18:05:12

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Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
	(b) (4)	
User entered '10'	System	06 Nov 2020 20:13:19
User entered '9'	System	04 Nov 2020 13:49:48
User entered '8'	System	03 Nov 2020 01:40:08
User entered '7'	System	21 Oct 2020 18:05:47
User entered '6'	System	14 Oct 2020 13:39:19
User entered '5'	System	07 Oct 2020 13:28:41
User entered '4'	System	28 Sep 2020 15:09:02
User entered '3'	System	11 Sep 2020 15:59:25
User entered '2'	System	11 Sep 2020 12:59:01
User entered '1'	System	10 Sep 2020 18:05:12

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Folder: SAE USA-US212-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:22:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:01:45
User entered '06/Nov/2020 20:13'	System	06 Nov 2020 20:13:19

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Form: Safety Report Form (10)

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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.	Michele Reynolds (b) (4)	22 Feb 2021 20:33:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:01:45
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 20:13:19