

US3512176 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:47:58

All time stamps listed in this document are displayed in GMT

US3512176

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:26:56

Generated On: 11 Aug 2021 22:47:58

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[Participant ID](#)

US3512176

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:27:31

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Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
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) 12 Feb 2021 21:27:31

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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) 12 Feb 2021 21:27:31

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:27:31

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	SHELLFISH ALLERGY
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	UNKNOWN POOL CHEMICALS ALLERGY
Start date (dd MMM yyyy)	15 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	ACID REFLUX
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 (4)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HEARTBURN
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 (5)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	COLON POLYPS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1980
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	VITAMIN D DEFICIENCY
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 (11)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	CATARACTS
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 (12)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	STROKE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	VERTIGO
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 (17)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	OSTEOARTHRITIS
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 (18)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	
Stop Year (derived)	

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Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HIGH TRIGLYCERIDES
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 (21)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HYPERTENSION
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 (24)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	SWELLING IN LOWER EXTREMITIES
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 (25)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Start Year (derived)	1981
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	POST-PARTUM DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1979
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 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	TONSILITIS
Start date (dd MMM yyyy)	UN UNK 1952
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 1952
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1952
Start Year (derived)	1952
Stop Month and Year (derived)	JAN 1952
Stop Year (derived)	1952

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1952
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 1952
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1952
Start Year (derived)	1952
Stop Month and Year (derived)	JAN 1952
Stop Year (derived)	1952

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Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1959
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 1959
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1959
Stop Year (derived)	1959



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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1959
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 1959
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1959
Stop Year (derived)	1959

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	TUBAL LIGATION
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 (32)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	BREAST REDUCTION
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	SHATTERED LEFT ELBOW
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	LIPOSUCTION WITH FULL BODY LIFT
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)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (37)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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



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Form: Medical History (38)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

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Form: Medical History (39)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	COLON RESECTION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3512176

Folder: Screening

Form: Medical History (40)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3512176

Folder: Screening

Form: Medical History (41)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

US3512176

Folder: Screening

Form: Medical History (42)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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

US3512176

Folder: Screening

Form: Medical History (43)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Condition	POST-MENOPAUSAL
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)	

US3512176

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	07:26 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 07:26
Height ( <i>xxx.x</i> )	60.25 in
Weight ( <i>xxx.x</i> )	212.4 lb
BMI ( <i>xxx.x</i> )	41.22402 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input 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)	

US3512176

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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



US3512176

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*) 29 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1998

Date of last menstruation unknown False

US3512176

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3512176

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	PARTICIPANT ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER (RESTAURANTS, COMMUNITY POOL); INTERACTS W/>5 PEOPLE A DAY OUTSIDE WORK OR HOME

US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 188367

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 ☒

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Height	ND - Not Done
Weight	ND - Not Done

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	07:26 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 07:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 09:38
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG



US3512176

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 AUG 2020

What was the treatment time? (00:00-23:59) 09:07 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 09:07

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

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 AUG 2020

Collection time (00:00-23:59)

07:59 (24 HR)

Collection date and time (derived)

29 AUG 2020 07:59

US3512176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:44	29 AUG 2020 07:44
Nasopharyngeal Swab 2	No		

US3512176

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

29 AUG 2020 09:39

PC Open Date & Time

29 AUG 2020 09:27

PC Close Date & Time

29 AUG 2020 11:57

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp 29 AUG 2020 20:04

PC Open Date & Time 29 AUG 2020 12:52

PC Close Date & Time 30 AUG 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 18:30

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

31 AUG 2020 22:28

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.2 °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 20:57

---

PC Open Date & Time

01 SEP 2020 12:00

---

PC Close Date & Time

02 SEP 2020 11:59

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US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 22:15

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

03 SEP 2020 21:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	04 SEP 2020 19:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 8

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 SEP 2020 07:03

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

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

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

PC Time Stamp 06 SEP 2020 22:11

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 10

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 SEP 2020 22:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 11

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	08 SEP 2020 21:46
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 12

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 09:40

PC Open Date & Time

29 AUG 2020 09:27

PC Close Date & Time

29 AUG 2020 11:57

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 23:02

PC Open Date & Time

29 AUG 2020 12:52

PC Close Date & Time

30 AUG 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 18:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 22:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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 20:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:16

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:11

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 09:40
PC Open Date & Time	29 AUG 2020 09:27
PC Close Date & Time	29 AUG 2020 11:57

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 23:03
PC Open Date & Time	29 AUG 2020 12:52
PC Close Date & Time	30 AUG 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 18:33
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 22:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:03
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:13
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

06 SEP 2020 07:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☒

PC Time Stamp

06 SEP 2020 22:11

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

07 SEP 2020 22:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

08 SEP 2020 21:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

09 SEP 2020 18:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

10 SEP 2020 22:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

11 SEP 2020 15:49

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

12 SEP 2020 23:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

13 SEP 2020 22:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(17)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

14 SEP 2020 21:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(18)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp

16 SEP 2020 02:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(19)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

---

PC Time Stamp

17 SEP 2020 05:59

---

PC Open Date & Time

16 SEP 2020 12:00

---

PC Close Date & Time

17 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(20)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

17 SEP 2020 21:52

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

06 SEP 2020 07:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

06 SEP 2020 22:11

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time Stamp

08 SEP 2020 21:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 22:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(14)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:49

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(15)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 23:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(16)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

13 SEP 2020 22:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(17)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(18)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 02:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(19)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 05:59

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(20)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:52

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(21)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time Stamp

18 SEP 2020 17:50

---

PC Open Date & Time

18 SEP 2020 12:00

---

PC Close Date & Time

19 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 06 SEP 2020 07:04

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 06 SEP 2020 22:12

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 SEP 2020 22:37

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp

08 SEP 2020 21:48

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 SEP 2020 18:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 06 SEP 2020 07:04

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 06 SEP 2020 22:12

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

---

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 07 SEP 2020 22:38

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 07:04
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 22:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 22:38
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 SEP 2020 21:48
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 18:25
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 22:20
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 15:49
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 23:16
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 16
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 22:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 17
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 21:33
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 18
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 02:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 19
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 05:59
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 20
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 21:52
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 21
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 17:50
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3512176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512176

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

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	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was study treatment given? Yes ☐  
No ☒

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

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

What was the study treatment? \_\_\_\_\_

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? \_\_\_\_\_

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

10:52 (24 HR)

Collection date and time (derived)

30 SEP 2020 10:52

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	30 SEP 2020 10:15
Nasopharyngeal Swab 2	No		



US3512176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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



US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:53
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

12:05 (24 HR)

Collection date and time (derived)

23 OCT 2020 12:05

US3512176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:32

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59



US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 15:44:55

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 18:23:37

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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	23 NOV 2020 04:06:13
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 18:30:08
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 DEC 2020 06:43:09
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 DEC 2020 01:58:15
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 00:41:00

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 DEC 2020 02:53:36
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 JAN 2021 04:30:55
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 03:32:04

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 JAN 2021 11:28:54
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 03:43:56

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:18:28

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 06:53:00

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:16:29

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 04:05:48
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 07:19:07

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 00:02:59
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 18:01:47

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 12:33:29

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 08:48:21

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 05:59:24

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 00:22:42

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**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

19 APR 2021 08:08:17

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 00:31:48

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 22:46:07

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 278

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 285

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 327

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 376

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 418

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 425

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

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15 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 NOV 2021 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

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06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 488

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

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10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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18 FEB 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

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25 FEB 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

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04 MAR 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

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11 MAR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

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14 MAR 2022 00:01

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18 MAR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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21 MAR 2022 00:01

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25 MAR 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

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28 MAR 2022 00:01

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01 APR 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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04 APR 2022 00:01

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08 APR 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

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11 APR 2022 00:01

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15 APR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

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25 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 APR 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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06 MAY 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 635

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 642

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

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17 JUN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 663

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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08 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

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22 JUL 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 698

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

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29 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

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05 AUG 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 712

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

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12 AUG 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

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19 AUG 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

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26 AUG 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

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02 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

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05 SEP 2022 00:01

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09 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 747

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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12 SEP 2022 00:01

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16 SEP 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 754

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

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23 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

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30 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

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07 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59



US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2022 23:59

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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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 ☐

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2022 00:01

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28 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3512176**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

**US3512176**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:47:58**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 07:18:10

US3512176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512176

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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*

US3512176

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

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*

US3512176

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 19:59:43

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 19:59:43

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3512176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3512176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	31 MAR 2021 10:26

US3512176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:04:34

Generated On: 11 Aug 2021 22:47:58

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*

US3512176

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:04:34

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3512176**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3512176**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Date of Contact	22 OCT 2020
Time of Contact	09:06
Date and Time of Contact (derived)	22 OCT 2020 09:06
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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"/>

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 22 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Date of Visit	23 OCT 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	23 OCT 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 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Date of Contact	27 JAN 2021
Time of Contact	08:40
Date and Time of Contact (derived)	27 JAN 2021 08:40
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	96.7 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 27 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.8 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 27 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Symptom Day

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

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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"/>

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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"/>

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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 ☐

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Date of Visit	27 JAN 2021
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	27 JAN 2021
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

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 OCT 2020
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)	

US3512176

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 21:24:44

Generated On: 11 Aug 2021 22:47:58

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 JAN 2021
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)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	SICKD1



US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:56
Height (xxx.x)	60.25 in
Weight (xxx.x)	96.1 kg
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3512176

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 OCT 2020

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	SICKD1

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JAN 2021
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 08:57
Height (xxx.x)	60.3 in
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3512176

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 JAN 2021

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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

Visit date (dd MMM yyyy)	
--------------------------	--

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

Folder OID	SICKD28
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US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Visit date (dd MMM yyyy)	
--------------------------	--

Was visit performed at the participant's home or at the clinic?	Home <input type="checkbox"/>
	Clinic <input type="checkbox"/>

Folder OID	SICKD28
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US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	3 FEB 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 12:49:33

Generated On: 11 Aug 2021 22:47:58

Date of updated informed consent ( <i>dd MMM yyyy</i> )	3 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	3 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" 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

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Height	60.25 in
Weight	209.4 lb
BMI (xxx.x)	40.64176

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Height	60.25 in
Weight	209.4 lb
BMI (xxx.x)	40.64176
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)	3 FEB 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 09:55
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Height	60.25 in
Weight	209.4 lb
BMI (xxx.x)	40.64176
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)	3 FEB 2021
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 11:24
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:30

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 10:50

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:27:30

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 FEB 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

3 FEB 2021 09:40

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 FEB 2021
Collection time (00:00 - 23:59)	09:35
Collection Date and Time (derived)	3 FEB 2021 09:35



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3512176

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:19
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

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)	3 MAR 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 10:45
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3512176

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512176

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 MAR 2021

What was the treatment time? (00:00-23:59) 10:12 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 10:12

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



US3512176

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:42:33

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 12:49:33

Generated On: 11 Aug 2021 22:47:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 12:49:33

Generated On: 11 Aug 2021 22:47:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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	OLD57

US3512176

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3512176

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:29:03

Generated On: 11 Aug 2021 22:47:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

10:26 (24 HR)

Collection date and time (derived)

31 MAR 2021 10:26

US3512176

Folder: **Unscheduled 25 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Visit Date	25 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False



US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:59 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:59
Temperature ( <i>xxx.x</i> )	98.7 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> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:27:31

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512176

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:26:56

Generated On: 11 Aug 2021 22:47:58

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	WORSENING HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	31 AUG 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)	20 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 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	INTERMITTENT FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	30 AUG 2020
Start time (00:00-23:59)	10:00 (24 HR)
AE start date and time (derived)	30 AUG 2020 10:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 JAN 2021
End time (00:00-23:59)	10:00 (24 HR)
AE End Date and Time (derived)	07 JAN 2021 10:00
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 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 (2)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID

Adverse event

SHOULDERS AND RIGHT HIP  
MUSCLE ACHES

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)

30 AUG 2020

Start time (00:00-23:59)

10:00 (24 HR)

AE start date and time (derived)

30 AUG 2020 10:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 SEP 2020

End time (00:00-23:59)

10:00 (24 HR)

AE End Date and Time (derived)

9 SEP 2020 10:00

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 (3)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	ELBOWS AND RIGHT HIP JOINT ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	30 AUG 2020
Start time (00:00-23:59)	10:00 (24 HR)
AE start date and time (derived)	30 AUG 2020 10:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 SEP 2020
End time (00:00-23:59)	10:00 (24 HR)
AE End Date and Time (derived)	7 SEP 2020 10:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	INTERMITTENT HIVES (FACE AND NECK)
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)	31 AUG 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)	7 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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	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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID

Adverse event

WORSENERD INTERMITTENT  
HEADACHES

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)

23 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	COVID LIKE ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 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)	07 JAN 2021
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 (10)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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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 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	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 (11)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID

Adverse event

VIRAL UPPER RESPIRATORY  
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)

25 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 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 (11)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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 (12)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	WORSENING ACID REFLEX
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)	25 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (12)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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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 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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

AEID	
Adverse event	WORSENING OSTEOARTHRITIS RIGHT HIP
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	22 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1980
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) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1978	
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"/>

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication ZOLOFT

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY/FIBROMYALGIA

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 (3)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1981
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication FERROUS FUMARATE

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 18

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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Name of Medication PRILOSEC OTC

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

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 (6)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

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 (7)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication FISH OIL

Prophylaxis Yes ☐  
No ☒

Indication HIGH TRIGLYCERIDES

Dose per administration 1200

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) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN JUN 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 16:44:20

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Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

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

EVERY 2 HOURS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SEASONAL INFLUENZA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication EQUATE ANTI ITCH  
DIPHENHYDRAMINE

Prophylaxis Yes ☐  
No ☒

Indication INTERMITTENT HIVES

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		7 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication HIVES

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication PRILOSEC OTC

Prophylaxis Yes ☐  
No ☒

Indication WORSENING ACID REFLUX

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

Dose per administration 750

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication VIRAL UPPER RESPIRATORY  
INFECTION

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OSTEOARTHRITIS  
RIGHT HIP

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 16:44:20

Generated On: 11 Aug 2021 22:47:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3512176

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 21:26:57

Generated On: 11 Aug 2021 22:47:58

---

Date of dosing discontinuation (dd MMM yyyy) 30 SEP 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE # 7

---

US3512176

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:47:58

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3512176 (Prod: Jacksonville Center for Clinical Research Center)

**US3512176**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:47:58**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'US3512176'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:45:43

US3512176

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:29:03



US3512176

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:45:44

US3512176

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	29 Aug 2020 13:29:03

**US3512176**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'SCRN'	System	29 Aug 2020 13:29:03

US3512176

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:45:45

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '71'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'YEARS'	System	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '71'	System	29 Aug 2020 13:29:38

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Female (F)'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22



US3512176

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'I'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:29:22



**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

**US3512176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:58**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	Allison Crain (b) (4)	29 Aug 2020 13:29:38

**US3512176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:58**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Aug 2020'	System	29 Aug 2020 13:29:38

**US3512176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:58**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2020'	System	29 Aug 2020 13:29:38

**US3512176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:58**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Amendment 3 (3)'	Allison Crain (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:58

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 13:29:38

**US3512176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:58**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 13:29:38



US3512176

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:45:44

**US3512176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:58**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'I'	System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:47:58

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:47:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:20

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:16:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:16:42
Data point term sent to Coder	System	29 Aug 2020 15:16:03
User entered 'shellfish allergy'	Taylor Johnson (b) (4)	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1965'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:48



**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1965'	System	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1965'	System	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:15:48

**US3512176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:15:48



US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
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 - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 06:21:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 06:21:35
Data point term sent to Coder	System	29 Aug 2020 15:17:04
User entered 'unknown pool chemicals allergy'	Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '15 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Aug 2020'	System	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2020'	System	29 Aug 2020 15:16:27



**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:16:27

**US3512176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:18:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:18:43
Data point term sent to Coder	System	29 Aug 2020 15:17:04
User entered 'acid reflux'	Taylor Johnson (b) (4)	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2018'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:16:49



**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2018'	System	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2018'	System	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:16:49

**US3512176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:11
Data point term sent to Coder	System	29 Aug 2020 15:18:06
User entered 'heartburn'	Taylor Johnson (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2018'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:21



**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2018'	System	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2018'	System	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:17:21

**US3512176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:18:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:18:43
Data point term sent to Coder	System	29 Aug 2020 15:18:06
User entered 'gallstones'	Taylor Johnson (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Taylor Johnson (b) (4)	29 Aug 2020 15:17:52
User entered 'un UNK 2018'	(b) (4)	
	Taylor Johnson (b) (4)	29 Aug 2020 15:17:35
	(b) (4)	



**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Taylor Johnson (b) (4)	29 Aug 2020 15:17:52
User entered 'un UNK 2018'	(b) (4)	
	Taylor Johnson (b) (4)	29 Aug 2020 15:17:35
	(b) (4)	

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 15:17:52
User entered 'Jan 2018'	System	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 15:17:52
User entered '2018'	System	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 15:17:52
User entered 'Jan 2018'	System	29 Aug 2020 15:17:35

**US3512176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 15:17:52
User entered '2018'	System	29 Aug 2020 15:17:35



US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:41
Data point term sent to Coder	System	29 Aug 2020 15:19:07
User entered 'irritable bowel syndrome'	Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un Feb 2020'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Feb 2020'	System	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2020'	System	29 Aug 2020 15:18:24



**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:18:24

**US3512176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:19:41
Data point term sent to Coder	System	29 Aug 2020 15:19:07
User entered 'colon polyps'	Taylor Johnson (b) (4)	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2016'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:18:43



**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2016'	System	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2016'	System	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:18:43

**US3512176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
Data point term sent to Coder	System	29 Aug 2020 15:20:07
User entered 'kidney stones'	Taylor Johnson (b) (4)	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:13



**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	Taylor Johnson (b) (4)	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:19:13

**US3512176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
Data point term sent to Coder	System	29 Aug 2020 15:20:07
User entered 'uterine fibroids'	Taylor Johnson (b) (4)	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:38



**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1980'	System	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1980'	System	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:19:38

**US3512176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:19:38



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Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:20:41
Data point term sent to Coder	System	29 Aug 2020 15:20:07
User entered 'vitamin d deficiency'	Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2015'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2015'	System	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2015'	System	29 Aug 2020 15:19:56



**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:19:56

**US3512176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
Data point term sent to Coder	System	29 Aug 2020 15:21:08
User entered 'cataracts'	Taylor Johnson (b) (4)	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2018'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:14



**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2018'	System	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2018'	System	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:20:14

**US3512176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
Data point term sent to Coder	System	29 Aug 2020 15:21:08
User entered 'nearsighted'	Taylor Johnson (b) (4)	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1960'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:41



**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1960'	System	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1960'	System	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:20:41

**US3512176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:21:41
Data point term sent to Coder	System	29 Aug 2020 15:21:08
User entered 'bilateral hearing loss'	Taylor Johnson (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1964'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:21:04



**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1964'	System	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1964'	System	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:21:04

**US3512176**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:21:04



US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:23:42
Data point term sent to Coder	System	29 Aug 2020 15:23:09
User entered 'headaches'	Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1960'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1960'	System	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1960'	System	29 Aug 2020 15:22:50



**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:22:50

**US3512176**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:23:42
Data point term sent to Coder	System	29 Aug 2020 15:23:09
User entered 'stroke'	Taylor Johnson (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2017'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:08



**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 15:23:08

**US3512176**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:24:42
Data point term sent to Coder	System	29 Aug 2020 15:24:11
User entered 'vertigo'	Taylor Johnson (b) (4)	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2018'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:19



**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:47:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2018'	System	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2018'	System	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:23:19

**US3512176**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
Data point term sent to Coder	System	29 Aug 2020 15:25:15
User entered 'osteoarthritis'	Taylor Johnson (b) (4)	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:36



**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1980'	System	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1980'	System	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:24:36

**US3512176**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:24:36



US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
Data point term sent to Coder	System	29 Aug 2020 15:25:13
User entered 'fibromyalgia'	Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1991'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1991'	System	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1991'	System	29 Aug 2020 15:24:51



**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:24:51

**US3512176**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:47:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Broken elbow - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:25:43
Data point term sent to Coder	System	29 Aug 2020 15:25:15
User entered 'broken left elbow'	Taylor Johnson (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2003'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:47:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2003'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:09



**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 15:25:09

**US3512176**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglycerides high - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:20:44
Data point term sent to Coder	System	29 Aug 2020 17:19:50
Coding entries removed.	Allison Crain (b) (4)	29 Aug 2020 17:19:27
User entered 'HIGH TRIGLYCERIDES' reason for change: Data Entry Error	Allison Crain (b) (4)	29 Aug 2020 17:19:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:43
Data point term sent to Coder	System	29 Aug 2020 15:26:16
User entered 'hypertriglyceridemia'	Taylor Johnson (b) (4)	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2010'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:29



**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2010'	System	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2010'	System	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:25:29

**US3512176**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:43
Data point term sent to Coder	System	29 Aug 2020 15:26:17
User entered 'hypothyroidism'	Taylor Johnson (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1978'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:52



**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1978'	System	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1978'	System	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:25:52

**US3512176**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:25:52



US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:26:44
Data point term sent to Coder	System	29 Aug 2020 15:26:17
User entered 'overweight'	Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1960'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1960'	System	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1960'	System	29 Aug 2020 15:26:06



**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:26:06

**US3512176**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:47:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:55:41
Data point term sent to Coder	System	29 Aug 2020 16:55:07
User entered 'HYPERTENSION' reason for change:	Allison Crain (b) (4)	29 Aug 2020 16:54:45
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	29 Aug 2020 15:27:18
User entered 'hyoertension'	Taylor Johnson (b) (4)	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:26:38



**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1980'	System	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1980'	System	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:26:38

**US3512176**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 05:09:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 05:09:41
Data point term sent to Coder	System	29 Aug 2020 15:27:18
User entered 'swelling in lower extremities'	Taylor Johnson (b) (4)	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 2018'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:06



**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2018'	System	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2018'	System	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:27:06

**US3512176**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:29:44
Data point term sent to Coder	System	29 Aug 2020 15:28:21
User entered 'anxiety'	Taylor Johnson (b) (4)	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1981'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:39



**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1981'	System	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1981'	System	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:27:39

**US3512176**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	29 Aug 2020 15:27:39



US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, LLT: Postpartum depression - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 15:29:44
Data point term sent to Coder	System	29 Aug 2020 15:28:21
User entered 'post-partum depression'	Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1979'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'un UNK 1980'	Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Taylor Johnson (b) (4)	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1979'	System	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1979'	System	29 Aug 2020 15:28:16



**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1980'	System	29 Aug 2020 15:28:16

**US3512176**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1980'	System	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:57:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:57:42
Data point term sent to Coder	System	29 Aug 2020 16:56:10
User entered 'TONSILITIS'	Allison Crain (b) (4)	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1952'	Allison Crain (b) (4)	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1952'	Allison Crain (b) (4)	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:55:21



**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1952'	System	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1952'	System	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1952'	System	29 Aug 2020 16:55:21

**US3512176**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1952'	System	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:57:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:57:42
Data point term sent to Coder	System	29 Aug 2020 16:56:13
User entered 'TONSILLECTOMY'	Allison Crain (b) (4)	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1952'	Allison Crain (b) (4)	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:56:01



**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1952'	Allison Crain (b) (4)	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1952'	System	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1952'	System	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1952'	System	29 Aug 2020 16:56:01

**US3512176**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1952'	System	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
Data point term sent to Coder	System	29 Aug 2020 16:57:14
User entered 'APPENDICITIS'	Allison Crain (b) (4)	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1959'	Allison Crain (b) (4)	29 Aug 2020 16:56:17



**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1959'	Allison Crain (b) (4)	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1959'	System	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1959'	System	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1959'	System	29 Aug 2020 16:56:17

**US3512176**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1959'	System	29 Aug 2020 16:56:17



US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
Data point term sent to Coder	System	29 Aug 2020 16:57:14
User entered 'APPENDECTOMY'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1959'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1959'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1959'	System	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1959'	System	29 Aug 2020 16:56:37



**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1959'	System	29 Aug 2020 16:56:37

**US3512176**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1959'	System	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:58:43
Data point term sent to Coder	System	29 Aug 2020 16:57:14
User entered 'TUBAL LIGATION'	Allison Crain (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 11 Aug 2021 22:47:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1982'	Allison Crain (b) (4)	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1982'	Allison Crain (b) (4)	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:56:56



**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1982'	System	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1982'	System	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1982'	System	29 Aug 2020 16:56:56

**US3512176**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1982'	System	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast reduction - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:59:44
Data point term sent to Coder	System	29 Aug 2020 16:58:18
User entered 'BREAST REDUCTION'	Allison Crain (b) (4)	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1985'	Allison Crain (b) (4)	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 16:57:27



**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1985'	Allison Crain (b) (4)	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1985'	System	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1985'	System	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1985'	System	29 Aug 2020 16:57:27

**US3512176**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1985'	System	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 22:31:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 22:31:42
Data point term sent to Coder	System	29 Aug 2020 16:58:18
User entered 'SHATTERED LEFT ELBOW'	Allison Crain (b) (4)	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2002'	Allison Crain (b) (4)	29 Aug 2020 16:58:10



**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2002'	System	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2002'	System	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 16:58:10

**US3512176**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 16:58:10



US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 11:45:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 11:45:36
Data point term sent to Coder	System	29 Aug 2020 16:59:19
User entered 'SHATTERED LEFT ELBOW REPAIR'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 16:58:32



**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 16:58:32

**US3512176**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:59:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 16:59:45
Data point term sent to Coder	System	29 Aug 2020 16:59:21
User entered 'GASTRIC BYPASS'	Allison Crain (b) (4)	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:59:11



**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2003'	System	29 Aug 2020 16:59:11

**US3512176**

**Folder: Screening**

**Form: Medical History (35)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2003'	System	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Liposuction, LLT: Liposuction - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:15:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:15:42
Data point term sent to Coder	System	29 Aug 2020 17:00:24
User entered 'LIPOSUCTION WITH FULL BODY LIFT'	Allison Crain (b) (4)	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2004'	Allison Crain (b) (4)	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 16:59:53



**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2004'	Allison Crain (b) (4)	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2004'	System	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2004'	System	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2004'	System	29 Aug 2020 16:59:53

**US3512176**

**Folder: Screening**

**Form: Medical History (36)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2004'	System	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
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)	29 Aug 2020 17:00:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:00:46
Data point term sent to Coder	System	29 Aug 2020 17:00:24
User entered 'LEFT KNEE REPLACEMENT'	Allison Crain (b) (4)	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2005'	Allison Crain (b) (4)	29 Aug 2020 17:00:13



**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2005'	Allison Crain (b) (4)	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2005'	System	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2005'	System	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2005'	System	29 Aug 2020 17:00:13

**US3512176**

**Folder: Screening**

**Form: Medical History (37)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2005'	System	29 Aug 2020 17:00:13



US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
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)	29 Aug 2020 17:02:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:02:46
Data point term sent to Coder	System	29 Aug 2020 17:01:25
User entered 'RIGHT KNEE REPLACEMENT'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2012'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2012'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2012'	System	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2012'	System	29 Aug 2020 17:00:32



**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2012'	System	29 Aug 2020 17:00:32

**US3512176**

**Folder: Screening**

**Form: Medical History (38)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2012'	System	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:37
Data point term sent to Coder	System	29 Aug 2020 17:03:27
User entered 'COLON RESECTION'	Allison Crain (b) (4)	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2017'	Allison Crain (b) (4)	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2017'	Allison Crain (b) (4)	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:02:33



**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 17:02:33

**US3512176**

**Folder: Screening**

**Form: Medical History (39)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
Query 'Per DM CLR : Please review the response in 'If No, what is the reason?' field in Childbearing Potential eCRF as it does not match with this corresponding procedure. Please reconcile and update data as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 12:03:17
User opened query 'Per DM CLR : Please review the response in 'If No, what is the reason?' field in Childbearing Potential eCRF as it does not match with this corresponding procedure. Please reconcile and update data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:39:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 17:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 17:04:37
Data point term sent to Coder	System	29 Aug 2020 17:03:29
User entered 'HYSTERECTOMY'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2017'	Allison Crain (b) (4)	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:02:50



**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2017'	Allison Crain (b) (4)	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2017'	System	29 Aug 2020 17:02:50

**US3512176**

**Folder: Screening**

**Form: Medical History (40)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2017'	System	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:36
Data point term sent to Coder	System	29 Aug 2020 17:03:29
User entered 'cholecystectomy'	Allison Crain (b) (4)	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019'	Allison Crain (b) (4)	29 Aug 2020 17:03:15



**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019'	Allison Crain (b) (4)	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 17:03:15

**US3512176**

**Folder: Screening**

**Form: Medical History (41)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 17:03:15



US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 17:04:37
Data point term sent to Coder	System	29 Aug 2020 17:04:31
User entered 'LEFT HIP REPLACEMENT'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 2019'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 17:03:34



**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 2019'	System	29 Aug 2020 17:03:34

**US3512176**

**Folder: Screening**

**Form: Medical History (42)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '2019'	System	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 11 Aug 2021 22:47:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:45:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:45:58
Data point term sent to Coder	System	19 Nov 2020 13:45:27
User entered 'POST-MENOPAUSAL'	Allison Crain (b) (4)	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1998'	Allison Crain (b) (4)	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	19 Nov 2020 13:44:30



**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'Jan 1998'	System	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '1998'	System	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	19 Nov 2020 13:44:30

**US3512176**

**Folder: Screening**

**Form: Medical History (43)**

**Generated On: 11 Aug 2021 22:47:58**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered empty.	System	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	Allison Crain (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '07:26'	Allison Crain (b) (4)	29 Aug 2020 17:05:14

**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '29 Aug 2020 07:26'	System	29 Aug 2020 17:05:14



US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '60.25' in	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14
DataPoint set to visible.	(b) (4) System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '212.4' lb	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14
DataPoint set to visible.	(b) (4) System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered '41.22402'	System	29 Aug 2020 17:05:14
DataPoint set to visible.	System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'kg/m2'	System	29 Aug 2020 17:05:14
DataPoint set to visible.	System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	Allison Crain (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14

**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14



**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'bpm'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	Allison Crain (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'breaths/min'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14

**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'mmHg'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:05:14

**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User entered 'mmHg'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56



**US3512176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56

**US3512176**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:30:35

US3512176

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	Allison Crain (b) (4)	29 Aug 2020 13:30:35

**US3512176**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:47:58**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	Allison Crain (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:07:26

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 07:42:49
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Added to MH' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:45:08
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 03:01:32
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

**US3512176**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:47:58**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:58

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:07:26



**US3512176**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:47:58**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:58

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'UN UNK 1998' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:42:54
User entered 'UN UNK 1988'	(b) (4)	
	Allison Crain (b) (4)	29 Aug 2020 17:07:26
	(b) (4)	

**US3512176**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:47:58**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11



US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

**US3512176**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:47:58**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11



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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

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)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'I'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'I'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:06:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'PARTICIPANT ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER (RESTAURANTS, COMMUNITY POOL); INTERACTS W/>5 PEOPLE A DAY OUTSIDE WORK OR HOME'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:11



US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30Sep2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:26:32
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30Sep2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Has been added to EDC' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:39:24
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30Sep2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:53:32
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:01

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:30:01

US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	29 Aug 2020 13:30:01

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'VISIT1'	System	29 Aug 2020 13:30:01

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '188367'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:30



US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:30

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:47:58**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:58

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:22:30
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 17:38:41
User entered 'No (N)'	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 17:38:37
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	03 Nov 2020 14:51:20
	System	19 Sep 2020 08:35:20
	System	19 Sep 2020 08:35:18

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14



US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '07:26'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '29 Aug 2020 07:26'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '98.2' F	Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14



**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '71'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'bpm'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '20'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'breaths/min'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '137'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '80'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14



**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '09:38'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '29 Aug 2020 09:38'	System	29 Aug 2020 17:10:51



US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '97.6' F	Allison Crain (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '64'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'bpm'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '16'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'breaths/min'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '153'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '95'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:10:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:30:09

US3512176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:30:09

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:37:44



**US3512176**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	Allison Crain (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '09:07'	Allison Crain (b) (4)	29 Aug 2020 13:37:44

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '29 Aug 2020 09:07'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'ONCE'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:07



US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:07

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '07:59'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:07

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '29 Aug 2020 07:59'	System	29 Aug 2020 17:11:07

US3512176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '29 Aug 2020'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:11:25

US3512176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '07:44'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '29 Aug 2020 07:44'	System	29 Aug 2020 17:11:25



US3512176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:11:25

US3512176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:11:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:11:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered empty.	System	29 Aug 2020 17:11:25

US3512176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 13:30:25

**US3512176**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	29 Aug 2020 13:30:25

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:38:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '63638700-1b9a-43a2-ac79-53072b5c79e0' User entered 'Yes (Y)'	System	29 Aug 2020 13:39:27
	System	29 Aug 2020 13:39:27



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '63638700-1b9a-43a2-ac79-53072b5c79e0' User entered '97.6'	System	29 Aug 2020 13:39:27
	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:16', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '63638700-1b9a-43a2-ac79-53072b5c79e0' User entered 'No (N)'	System	29 Aug 2020 13:39:27
	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '63638700-1b9a-43a2-ac79-53072b5c79e0' User entered '29 Aug 2020 09:39'	System	29 Aug 2020 13:39:27
	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 09:27'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 11:57'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T20:03:31', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45d86c0-5c44-4968-84eb-0ebfb0b19183' User entered 'Yes (Y)'	System	30 Aug 2020 00:04:10
	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T20:03:40', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45d86c0-5c44-4968-84eb-0ebfb0b19183' User entered '97.8'	System	30 Aug 2020 00:04:10
	System	30 Aug 2020 00:04:10



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T20:03:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45d86c0-5c44-4968-84eb-0ebfb0b19183' User entered 'No (N)'	System	30 Aug 2020 00:04:10
	System	30 Aug 2020 00:04:10

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T20:04:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45d86c0-5c44-4968-84eb-0ebfb0b19183' User entered '29 Aug 2020 20:04'	System	30 Aug 2020 00:04:10
	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 12:52'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 2'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:29:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56' User entered 'Yes (Y)'	System	30 Aug 2020 22:30:27
	System	30 Aug 2020 22:30:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:29:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56' User entered '96.5'	System	30 Aug 2020 22:30:27
	System	30 Aug 2020 22:30:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:29:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56'	System	30 Aug 2020 22:30:27
User entered 'Yes (Y)'	System	30 Aug 2020 22:30:27



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and discussed medication.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 01:41:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Sheldon Warren (b) (4)	08 Sep 2020 18:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56'	System	30 Aug 2020 22:30:27
User entered '1'	System	30 Aug 2020 22:30:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56' User entered '0'	System	30 Aug 2020 22:30:27
	System	30 Aug 2020 22:30:27

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:26', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'db36a172-1ff8-4e09-8f75-26d798996f56'	System	30 Aug 2020 22:30:27
User entered '30 Aug 2020 18:30'	System	30 Aug 2020 22:30:27

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 3'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2' User entered 'Yes (Y)'	System	01 Sep 2020 02:28:50
	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2' User entered '97.8'	System	01 Sep 2020 02:28:50
	System	01 Sep 2020 02:28:50



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:27', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2'	System	01 Sep 2020 02:28:50
User entered 'Yes (Y)'	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and discussed medication.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 01:41:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2' User entered '1'	Sheldon Warren (b) (4)	08 Sep 2020 18:38:17
	System	01 Sep 2020 02:28:50
	System	01 Sep 2020 02:28:50
	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2'	System	01 Sep 2020 02:28:50
User entered '0'	System	01 Sep 2020 02:28:50

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '803a980d-ff72-45cc-ac6b-e7c1b5dde6c2'	System	01 Sep 2020 02:28:50
User entered '31 Aug 2020 22:28'	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 4'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a03458bc-1bf8-4322-a51e-7c0e73d64ce8' User entered 'Yes (Y)'	System	02 Sep 2020 00:57:44
	System	02 Sep 2020 00:57:44



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a03458bc-1bf8-4322-a51e-7c0e73d64ce8' User entered '96.2'	System	02 Sep 2020 00:57:44
	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:29', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a03458bc-1bf8-4322-a51e-7c0e73d64ce8' User entered 'No (N)'	System	02 Sep 2020 00:57:44
	System	02 Sep 2020 00:57:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a03458bc-1bf8-4322-a51e-7c0e73d64ce8' User entered '01 Sep 2020 20:57'	System	02 Sep 2020 00:57:44
	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 5'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:15:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2cc1859c-8677-4296-b139-5a6a07406b32' User entered 'Yes (Y)'	System	03 Sep 2020 02:15:58
	System	03 Sep 2020 02:15:58

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:15:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2cc1859c-8677-4296-b139-5a6a07406b32' User entered '97.5'	System	03 Sep 2020 02:15:58
	System	03 Sep 2020 02:15:58



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:15:42', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2cc1859c-8677-4296-b139-5a6a07406b32'	System	03 Sep 2020 02:15:58
User entered 'No (N)'	System	03 Sep 2020 02:15:58

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:15:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2cc1859c-8677-4296-b139-5a6a07406b32'	System	03 Sep 2020 02:15:58
User entered '02 Sep 2020 22:15'	System	03 Sep 2020 02:15:58

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 6'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:10:19', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '18c8cda6-cc63-45eb-993b-cbe125fb8d71' User entered 'Yes (Y)'	System	04 Sep 2020 01:10:43
	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:10:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '18c8cda6-cc63-45eb-993b-cbe125fb8d71' User entered '97.3'	System	04 Sep 2020 01:10:43
	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:10:34', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '18c8cda6-cc63-45eb-993b-cbe125fb8d71' User entered 'No (N)'	System	04 Sep 2020 01:10:43
	System	04 Sep 2020 01:10:43



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:10:40', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '18c8cda6-cc63-45eb-993b-cbe125fb8d71' User entered '03 Sep 2020 21:10'	System	04 Sep 2020 01:10:43
	System	04 Sep 2020 01:10:43

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 7'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered 'Yes (Y)'	System	04 Sep 2020 23:02:19
	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered '96.5'	System	04 Sep 2020 23:02:19
	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:51', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered 'Yes (Y)'	System	04 Sep 2020 23:02:19
	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered '1'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:49:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Sep 2020 23:02:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered '1'	System	04 Sep 2020 23:02:19
User entered '1'	System	04 Sep 2020 23:02:19



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:01:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered '0'	System	04 Sep 2020 23:02:19
	System	04 Sep 2020 23:02:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cda99026-e66f-40e9-8ddf-7f510567da8d' User entered '04 Sep 2020 19:02'	System	04 Sep 2020 23:02:19
	System	04 Sep 2020 23:02:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:02:19
User entered 'Day 8'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:02:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555' User entered 'Yes (Y)'	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:03:42', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555' User entered '97.5'	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:03:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555'	System	06 Sep 2020 11:03:53
User entered 'Yes (Y)'	System	06 Sep 2020 11:03:53



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Allison Crain (b) (4)	19 Nov 2020 13:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:03:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555'	(b) (4)	
User entered '1'	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:03:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555' User entered '0'	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:03:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '64450cc2-9507-44b7-934e-5d040f84e555' User entered '06 Sep 2020 07:03'	System	06 Sep 2020 11:03:53
	System	06 Sep 2020 11:03:53

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 23:02:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:02:19
User entered 'Day 9'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:10:36', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7' User entered 'Yes (Y)'	System	07 Sep 2020 02:11:17
	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:10:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7' User entered '96.9'	System	07 Sep 2020 02:11:17
	System	07 Sep 2020 02:11:17



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:10:53', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7'	System	07 Sep 2020 02:11:17
User entered 'Yes (Y)'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:49:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7'	System	07 Sep 2020 02:11:17
User entered '1'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:26
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Allison Crain (b) (4)	19 Nov 2020 13:49:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7'	(b) (4)	
User entered '1'	System	07 Sep 2020 02:11:17
	System	07 Sep 2020 02:11:17
	System	07 Sep 2020 02:11:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd580d928-8487-4f3f-bd5b-8d07f2564ae7' User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:11:17
	System	07 Sep 2020 02:11:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:02:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:03:53
User entered 'Day 10'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:36:45', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	System	08 Sep 2020 02:37:12
User entered 'Yes (Y)'	System	08 Sep 2020 02:37:12



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:36:51', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	System	08 Sep 2020 02:37:12
User entered '97.6'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:36:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	System	08 Sep 2020 02:37:12
User entered 'Yes (Y)'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Allison Crain (b) (4)	19 Nov 2020 13:49:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:01', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	(b) (4)	
User entered '1'	System	08 Sep 2020 02:37:12
	System	08 Sep 2020 02:37:12
	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:01', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	System	08 Sep 2020 02:37:12
User entered '0'	System	08 Sep 2020 02:37:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7917f0e5-6080-47dd-83e0-80ffde541a44'	System	08 Sep 2020 02:37:12
User entered '07 Sep 2020 22:37'	System	08 Sep 2020 02:37:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:03:53

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	07 Sep 2020 02:11:17
User entered 'Day 11'	System	07 Sep 2020 02:11:17



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2' User entered 'Yes (Y)'	System	09 Sep 2020 01:46:49
	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:20', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2' User entered '96.3'	System	09 Sep 2020 01:46:49
	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2'	System	09 Sep 2020 01:46:49
User entered 'Yes (Y)'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed. Please see ConMed: ADVIL' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 07:36:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2' User entered '1'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:49:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Sep 2020 01:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2' User entered '1'	System	09 Sep 2020 01:46:49
User entered '1'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2' User entered '0'	System	09 Sep 2020 01:46:49
	System	09 Sep 2020 01:46:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:45', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c515e72b-e45b-480b-b1f2-f83f5af5a2f2'	System	09 Sep 2020 01:46:49
User entered '08 Sep 2020 21:46'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:11:17



US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	08 Sep 2020 02:37:12
User entered 'Day 12'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:24:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b35aa7e5-bc25-4501-881c-39ef6ca774c8' User entered 'Yes (Y)'	System	09 Sep 2020 22:25:09
	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:24:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b35aa7e5-bc25-4501-881c-39ef6ca774c8' User entered '96.4'	System	09 Sep 2020 22:25:09
	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:24:58', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b35aa7e5-bc25-4501-881c-39ef6ca774c8'	System	09 Sep 2020 22:25:09
User entered 'No (N)'	System	09 Sep 2020 22:25:09

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b35aa7e5-bc25-4501-881c-39ef6ca774c8' User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:09
	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 02:37:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '66545fed-9e5a-441b-a902-69903a3b9758'	System	29 Aug 2020 13:40:15
User entered 'None (1)'	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:53', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '66545fed-9e5a-441b-a902-69903a3b9758' User entered 'No (N)'	System	29 Aug 2020 13:40:15
	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:39:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '66545fed-9e5a-441b-a902-69903a3b9758' User entered 'No (N)'	System	29 Aug 2020 13:40:15
	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '66545fed-9e5a-441b-a902-69903a3b9758'	System	29 Aug 2020 13:40:15
User entered 'None (1)'	System	29 Aug 2020 13:40:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '66545fed-9e5a-441b-a902-69903a3b9758' User entered '29 Aug 2020 09:40'	System	29 Aug 2020 13:40:15
	System	29 Aug 2020 13:40:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 09:27'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 11:57'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:02', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6ab0c35-3b9b-43bd-9c8d-227a422ab7ce'	System	30 Aug 2020 03:02:26
User entered 'None (1)'	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6ab0c35-3b9b-43bd-9c8d-227a422ab7ce' User entered 'No (N)'	System	30 Aug 2020 03:02:26
	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6ab0c35-3b9b-43bd-9c8d-227a422ab7ce' User entered 'No (N)'	System	30 Aug 2020 03:02:26
	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:14', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6ab0c35-3b9b-43bd-9c8d-227a422ab7ce'	System	30 Aug 2020 03:02:26
User entered 'None (1)'	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6ab0c35-3b9b-43bd-9c8d-227a422ab7ce' User entered '29 Aug 2020 23:02'	System	30 Aug 2020 03:02:26
	System	30 Aug 2020 03:02:26

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 12:52'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 2'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a421379a-ff36-40bb-829f-c3de914c8532'	System	30 Aug 2020 22:31:12
User entered 'None (1)'	System	30 Aug 2020 22:31:12

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a421379a-ff36-40bb-829f-c3de914c8532'	System	30 Aug 2020 22:31:12
User entered 'No (N)'	System	30 Aug 2020 22:31:12

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:52', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a421379a-ff36-40bb-829f-c3de914c8532'	System	30 Aug 2020 22:31:12
User entered 'No (N)'	System	30 Aug 2020 22:31:12

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:30:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a421379a-ff36-40bb-829f-c3de914c8532'	System	30 Aug 2020 22:31:12
User entered 'None (1)'	System	30 Aug 2020 22:31:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:31:10', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a421379a-ff36-40bb-829f-c3de914c8532'	System	30 Aug 2020 22:31:12
User entered '30 Aug 2020 18:31'	System	30 Aug 2020 22:31:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 3'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:28:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4fc2cfff-65dd-4d6a-b045-09d127c6d237'	System	01 Sep 2020 02:29:14
User entered 'None (1)'	System	01 Sep 2020 02:29:14

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4fc2cfff-65dd-4d6a-b045-09d127c6d237'	System	01 Sep 2020 02:29:14
User entered 'No (N)'	System	01 Sep 2020 02:29:14

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4fc2cfff-65dd-4d6a-b045-09d127c6d237'	System	01 Sep 2020 02:29:14
User entered 'No (N)'	System	01 Sep 2020 02:29:14

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:07', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4fc2cfff-65dd-4d6a-b045-09d127c6d237'	System	01 Sep 2020 02:29:14
User entered 'None (1)'	System	01 Sep 2020 02:29:14

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:11', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4fc2cfff-65dd-4d6a-b045-09d127c6d237'	System	01 Sep 2020 02:29:14
User entered '31 Aug 2020 22:29'	System	01 Sep 2020 02:29:14

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 4'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7f73c125-9b06-4c2c-a2bc-3f2c1d4117ed'	System	02 Sep 2020 00:58:07
User entered 'None (1)'	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7f73c125-9b06-4c2c-a2bc-3f2c1d4117ed' User entered 'No (N)'	System	02 Sep 2020 00:58:07
	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:53', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7f73c125-9b06-4c2c-a2bc-3f2c1d4117ed' User entered 'No (N)'	System	02 Sep 2020 00:58:07
	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:57:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7f73c125-9b06-4c2c-a2bc-3f2c1d4117ed' User entered 'None (1)'	System	02 Sep 2020 00:58:07
	System	02 Sep 2020 00:58:07

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T20:58:05', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7f73c125-9b06-4c2c-a2bc-3f2c1d4117ed' User entered '01 Sep 2020 20:58'	System	02 Sep 2020 00:58:07
	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 5'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4cbe7615-77ac-4a5b-ae60-7df0dca2d842'	System	03 Sep 2020 02:16:30
User entered 'None (1)'	System	03 Sep 2020 02:16:30

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:05', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4cbe7615-77ac-4a5b-ae60-7df0dca2d842' User entered 'No (N)'	System	03 Sep 2020 02:16:30
	System	03 Sep 2020 02:16:30

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:08', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4cbe7615-77ac-4a5b-ae60-7df0dca2d842'	System	03 Sep 2020 02:16:30
User entered 'No (N)'	System	03 Sep 2020 02:16:30

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4cbe7615-77ac-4a5b-ae60-7df0dca2d842'	System	03 Sep 2020 02:16:30
User entered 'None (1)'	System	03 Sep 2020 02:16:30

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4cbe7615-77ac-4a5b-ae60-7df0dca2d842'	System	03 Sep 2020 02:16:30
User entered '02 Sep 2020 22:16'	System	03 Sep 2020 02:16:30

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 6'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:10:53', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '04be8353-5f66-4b22-ad4d-6ff769d3f18f' User entered 'None (1)'	System	04 Sep 2020 01:12:00
	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:11:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '04be8353-5f66-4b22-ad4d-6ff769d3f18f' User entered 'No (N)'	System	04 Sep 2020 01:12:00
	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:11:23', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '04be8353-5f66-4b22-ad4d-6ff769d3f18f' User entered 'No (N)'	System	04 Sep 2020 01:12:00
	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:11:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '04be8353-5f66-4b22-ad4d-6ff769d3f18f' User entered 'None (1)'	System	04 Sep 2020 01:12:00
	System	04 Sep 2020 01:12:00

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:11:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '04be8353-5f66-4b22-ad4d-6ff769d3f18f' User entered '03 Sep 2020 21:11'	System	04 Sep 2020 01:12:00
	System	04 Sep 2020 01:12:00

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 7'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'bc553198-bef1-4711-9e9d-2b83dd99c9e9'	System	04 Sep 2020 23:02:39
User entered 'None (1)'	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:20', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'bc553198-bef1-4711-9e9d-2b83dd99c9e9' User entered 'No (N)'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:23', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'bc553198-bef1-4711-9e9d-2b83dd99c9e9' User entered 'No (N)'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

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 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:29', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'bc553198-bef1-4711-9e9d-2b83dd99c9e9'	System	04 Sep 2020 23:02:39
User entered 'None (1)'	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'bc553198-bef1-4711-9e9d-2b83dd99c9e9' User entered '04 Sep 2020 19:02'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:19', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:33', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'None (0)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered 'No (N)'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T09:40:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4774b189-640f-43e4-a1c8-f6b3c41e857a' User entered '29 Aug 2020 09:40'	System	29 Aug 2020 13:40:53
	System	29 Aug 2020 13:40:53



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 09:27'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 11:57'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:52', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:02:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'None (0)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:03:01', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered 'No (N)'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-29T23:03:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd0a0a73a-14e2-43a0-a167-10a91d44197d' User entered '29 Aug 2020 23:03'	System	30 Aug 2020 03:03:16
	System	30 Aug 2020 03:03:16

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '29 Aug 2020 12:52'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 2'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:31:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b' User entered 'None (0)'	System	30 Aug 2020 22:33:15
	System	30 Aug 2020 22:33:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:31:29', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b'	System	30 Aug 2020 22:33:15
User entered 'Some interference with activity (2)'	System	30 Aug 2020 22:33:15



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:31:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b'	System	30 Aug 2020 22:33:15
User entered 'Some interference with activity (2)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:32:31', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b'	System	30 Aug 2020 22:33:15
User entered 'Some interference with activity (2)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:32:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b' User entered 'None (0)'	System	30 Aug 2020 22:33:15
	System	30 Aug 2020 22:33:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:32:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b' User entered 'None (0)'	System	30 Aug 2020 22:33:15
	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:32:51', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b' User entered 'No (N)'	System	30 Aug 2020 22:33:15
	System	30 Aug 2020 22:33:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-30T18:33:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f400bb1c-9302-4016-b515-7fec3620e17b' User entered '30 Aug 2020 18:33'	System	30 Aug 2020 22:33:15
	System	30 Aug 2020 22:33:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 13:37:44



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 3'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:26', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146'	System	01 Sep 2020 02:30:13
User entered 'No interference with activity (1)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:32', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146'	System	01 Sep 2020 02:30:13
User entered 'No interference with activity (1)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered 'None (0)'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered 'None (0)'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered 'None (0)'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:52', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered 'None (0)'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:29:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered 'No (N)'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-08-31T22:30:11', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '48d76b2d-51f4-48ad-aba1-29cb72dbb146' User entered '31 Aug 2020 22:30'	System	01 Sep 2020 02:30:13
	System	01 Sep 2020 02:30:13

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 4'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:01:58', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50'	System	02 Sep 2020 01:03:17
User entered 'No interference with activity (1)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:02:11', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50'	System	02 Sep 2020 01:03:17
User entered 'Significant; prevents daily activity (3)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:02:27', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50'	System	02 Sep 2020 01:03:17
User entered 'Significant; prevents daily activity (3)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:02:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50' User entered 'None (0)'	System	02 Sep 2020 01:03:17
	System	02 Sep 2020 01:03:17



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:02:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50'	System	02 Sep 2020 01:03:17
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:03:02', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50' User entered 'None (0)'	System	02 Sep 2020 01:03:17
	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:03:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50' User entered 'No (N)'	System	02 Sep 2020 01:03:17
	System	02 Sep 2020 01:03:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-01T21:03:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '3bfb85da-69a5-4c36-a7ba-4e803f6e0b50' User entered '01 Sep 2020 21:03'	System	02 Sep 2020 01:03:17
	System	02 Sep 2020 01:03:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 5'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358' User entered 'None (0)'	System	03 Sep 2020 02:17:40
	System	03 Sep 2020 02:17:40



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358'	System	03 Sep 2020 02:17:40
User entered 'Some interference with activity (2)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:16:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358'	System	03 Sep 2020 02:17:40
User entered 'Some interference with activity (2)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:17:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358'	System	03 Sep 2020 02:17:40
User entered 'No interference with activity (1)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:17:16', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358' User entered 'None (0)'	System	03 Sep 2020 02:17:40
	System	03 Sep 2020 02:17:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:17:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358' User entered 'None (0)'	System	03 Sep 2020 02:17:40
	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:17:27', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358' User entered 'No (N)'	System	03 Sep 2020 02:17:40
	System	03 Sep 2020 02:17:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-02T22:17:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '9a6163f5-29b8-4fdd-afa1-4b88b6ed8358' User entered '02 Sep 2020 22:17'	System	03 Sep 2020 02:17:40
	System	03 Sep 2020 02:17:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 13:37:44



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 6'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:21', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f'	System	04 Sep 2020 01:13:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:31', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:46', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:52', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'None (0)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:12:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'None (0)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:13:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered 'No (N)'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-03T21:13:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1ee5260f-e725-4b40-8862-5b65699ce04f' User entered '03 Sep 2020 21:13'	System	04 Sep 2020 01:13:18
	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 7'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'No interference with activity (1)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:02:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:05', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37



US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'None (0)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'None (0)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:21', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered 'No (N)'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-04T19:03:33', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0216a01f-2ba3-49c7-9819-018ff8872611' User entered '04 Sep 2020 19:03'	System	04 Sep 2020 23:03:37
	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 13:37:44

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 01:13:18
User entered 'Day 8'	System	04 Sep 2020 01:13:18



US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:02:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4b470e63-f9cf-4fc0-b4f2-d4ccc8b5a982'	System	06 Sep 2020 11:02:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 11:02:55

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:02:46', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4b470e63-f9cf-4fc0-b4f2-d4ccc8b5a982' User entered '06 Sep 2020 07:02'	System	06 Sep 2020 11:02:55
	System	06 Sep 2020 11:02:55

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:03:37
User entered 'Day 9'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7856b270-c1f9-4a37-9aa2-5736343b92db'	System	07 Sep 2020 02:11:43
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		07 Sep 2020 02:11:43

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:40', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7856b270-c1f9-4a37-9aa2-5736343b92db' User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:11:43
	System	07 Sep 2020 02:11:43

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:03:37



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:02:55
User entered 'Day 10'	System	06 Sep 2020 11:02:55

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2c33b5fc-a0ac-48d3-b4bc-91682706638d' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	08 Sep 2020 02:37:29
	System	08 Sep 2020 02:37:29

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2c33b5fc-a0ac-48d3-b4bc-91682706638d' User entered '07 Sep 2020 22:37'	System	08 Sep 2020 02:37:29
	System	08 Sep 2020 02:37:29

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:02:55

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:02:55

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	07 Sep 2020 02:11:43
User entered 'Day 11'	System	07 Sep 2020 02:11:43

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:46:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a1a86924-bba4-43bf-9544-bf07a1622968'	System	09 Sep 2020 01:47:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Sep 2020 01:47:09



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:47:05', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a1a86924-bba4-43bf-9544-bf07a1622968' User entered '08 Sep 2020 21:47'	System	09 Sep 2020 01:47:09
	System	09 Sep 2020 01:47:09

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:11:43

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:11:43

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	08 Sep 2020 02:37:29
User entered 'Day 12'	System	08 Sep 2020 02:37:29

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:10', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f94928ae-9599-4c15-8d28-74eb92860219'	System	09 Sep 2020 22:25:17
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:25:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f94928ae-9599-4c15-8d28-74eb92860219' User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:17
	System	09 Sep 2020 22:25:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 02:37:29

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 02:37:29



US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 01:47:09
User entered 'Day 13'	System	09 Sep 2020 01:47:09

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:11', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6b6e83c-578c-40de-b3a0-7dc8106054f8'	System	11 Sep 2020 02:20:22
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:20:22

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e6b6e83c-578c-40de-b3a0-7dc8106054f8' User entered '10 Sep 2020 22:20'	System	11 Sep 2020 02:20:22
	System	11 Sep 2020 02:20:22

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:47:09

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:47:09

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 22:25:17
User entered 'Day 14'	System	09 Sep 2020 22:25:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:48:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a3aa8b8b-ed6-4a76-ab78-282f501a6cee'	System	11 Sep 2020 19:49:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:49:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:49:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a3aa8b8b-ed6-4a76-ab78-282f501a6cee'	System	11 Sep 2020 19:49:03
User entered '11 Sep 2020 15:49'	System	11 Sep 2020 19:49:03



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 22:25:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 22:25:17

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 02:20:22
User entered 'Day 15'	System	11 Sep 2020 02:20:22

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(15)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:15:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '5e3d826b-8d01-47c3-a4ff-bb26a9a1f5f3'	System	13 Sep 2020 03:15:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 03:15:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:15:47', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '5e3d826b-8d01-47c3-a4ff-bb26a9a1f5f3' User entered '12 Sep 2020 23:15'	System	13 Sep 2020 03:15:49
	System	13 Sep 2020 03:15:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:20:22

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:20:22

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 19:49:03
User entered 'Day 16'	System	11 Sep 2020 19:49:03



US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'fb549208-3ed6-4b9d-855c-b05184f79064'	System	14 Sep 2020 02:31:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'fb549208-3ed6-4b9d-855c-b05184f79064'	System	14 Sep 2020 02:31:27
User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(16)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:49:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:49:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	13 Sep 2020 03:15:49
User entered 'Day 17'	System	13 Sep 2020 03:15:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0626ffd2-4400-40a0-badc-90c7898c5c6b' User entered 'No interference with activity (1)'	System	15 Sep 2020 01:33:18
	System	15 Sep 2020 01:33:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0626ffd2-4400-40a0-badc-90c7898c5c6b' User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:18
	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(17)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 03:15:49



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 03:15:49

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(18)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	14 Sep 2020 02:31:27
User entered 'Day 18'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(18)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:55:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f7e28e0c-ac03-4dee-a9fc-1f328816d0b1'	System	16 Sep 2020 06:55:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Sep 2020 06:55:34

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(18)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:55:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f7e28e0c-ac03-4dee-a9fc-1f328816d0b1' User entered '16 Sep 2020 02:55'	System	16 Sep 2020 06:55:34
	System	16 Sep 2020 06:55:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 02:31:27

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(19)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	15 Sep 2020 01:33:18
User entered 'Day 19'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(19)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '835d4ac9-5d5f-4661-b8ed-20c4be58aa54'	System	17 Sep 2020 09:59:30
User entered 'No interference with activity (1)'	System	17 Sep 2020 09:59:30



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '835d4ac9-5d5f-4661-b8ed-20c4be58aa54' User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:30
	System	17 Sep 2020 09:59:30

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(19)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache\_Day(20)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	16 Sep 2020 06:55:34
User entered 'Day 20'	System	16 Sep 2020 06:55:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:27', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a0d46133-bfc7-42bc-8b08-74ca092df674' User entered 'None (0)'	System	18 Sep 2020 01:52:34
	System	18 Sep 2020 01:52:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a0d46133-bfc7-42bc-8b08-74ca092df674'	System	18 Sep 2020 01:52:34
User entered '17 Sep 2020 21:52'	System	18 Sep 2020 01:52:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 06:55:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 06:55:34



US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 01:13:18
User entered 'Day 8'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:01', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2bd76b15-e673-4c65-9296-afa1f94a407f' User entered 'Significant; prevents daily activity (3)'	System	06 Sep 2020 11:04:15
	System	06 Sep 2020 11:04:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2bd76b15-e673-4c65-9296-afa1f94a407f' User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:15
	System	06 Sep 2020 11:04:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:03:37
User entered 'Day 9'	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f523710e-f970-4555-afdf-2b74f1a3c9fb' User entered 'Significant; prevents daily activity (3)'	System	07 Sep 2020 02:12:00
	System	07 Sep 2020 02:12:00

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:11:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f523710e-f970-4555-afdf-2b74f1a3c9fb' User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:12:00
	System	07 Sep 2020 02:12:00



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:04:15
User entered 'Day 10'	System	06 Sep 2020 11:04:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:34', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '5a36626e-1c39-4a4a-bbba-199ae3336dd6' User entered 'Some interference with activity (2)'	System	08 Sep 2020 02:37:39
	System	08 Sep 2020 02:37:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '5a36626e-1c39-4a4a-bbba-199ae3336dd6' User entered '07 Sep 2020 22:37'	System	08 Sep 2020 02:37:39
	System	08 Sep 2020 02:37:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:04:15

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:04:15

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	07 Sep 2020 02:12:00
User entered 'Day 11'	System	07 Sep 2020 02:12:00



US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:47:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ebd6b000-2de2-4d45-b2e6-e6a79fc82743'	System	09 Sep 2020 01:47:26
User entered 'Some interference with activity (2)'	System	09 Sep 2020 01:47:26

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:47:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ebd6b000-2de2-4d45-b2e6-e6a79fc82743' User entered '08 Sep 2020 21:47'	System	09 Sep 2020 01:47:26
	System	09 Sep 2020 01:47:26

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:12:00

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	08 Sep 2020 02:37:39
User entered 'Day 12'	System	08 Sep 2020 02:37:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:20', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '290ac163-d87a-4b94-a568-a50528293721'	System	09 Sep 2020 22:25:25
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:25:25

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '290ac163-d87a-4b94-a568-a50528293721' User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:25
	System	09 Sep 2020 22:25:25

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 02:37:39



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 02:37:39

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 01:47:26
User entered 'Day 13'	System	09 Sep 2020 01:47:26

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:26', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ccc8e07a-f0ab-4c1e-9e2f-6de301d81680'	System	11 Sep 2020 02:20:36
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:20:36

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:32', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ccc8e07a-f0ab-4c1e-9e2f-6de301d81680' User entered '10 Sep 2020 22:20'	System	11 Sep 2020 02:20:36
	System	11 Sep 2020 02:20:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:47:26

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:47:26

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(14)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 22:25:25
User entered 'Day 14'	System	09 Sep 2020 22:25:25

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(14)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:49:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '915ab2cf-e70a-42c1-93f4-724649634618' User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:49:11
	System	11 Sep 2020 19:49:11



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:49:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '915ab2cf-e70a-42c1-93f4-724649634618' User entered '11 Sep 2020 15:49'	System	11 Sep 2020 19:49:11
	System	11 Sep 2020 19:49:11

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 22:25:25

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 22:25:25

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(15)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 02:20:36
User entered 'Day 15'	System	11 Sep 2020 02:20:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:15:57', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '07fe122b-4c13-4eb4-a99a-873522b190ac'	System	13 Sep 2020 03:16:03
User entered 'Some interference with activity (2)'	System	13 Sep 2020 03:16:03

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(15)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:16:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '07fe122b-4c13-4eb4-a99a-873522b190ac' User entered '12 Sep 2020 23:16'	System	13 Sep 2020 03:16:03
	System	13 Sep 2020 03:16:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:20:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:20:36



US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(16)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 19:49:11
User entered 'Day 16'	System	11 Sep 2020 19:49:11

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(16)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd3518061-a520-4f5b-be68-a930851df300'	System	14 Sep 2020 02:31:36
User entered 'No interference with activity (1)'	System	14 Sep 2020 02:31:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:34', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd3518061-a520-4f5b-be68-a930851df300'	System	14 Sep 2020 02:31:36
User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:49:11

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:49:11

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(17)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	13 Sep 2020 03:16:03
User entered 'Day 17'	System	13 Sep 2020 03:16:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '141beb2d-b956-4a67-bd8d-b11add3acf36'	System	15 Sep 2020 01:33:31
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:33:31

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:29', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '141beb2d-b956-4a67-bd8d-b11add3acf36' User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:31
	System	15 Sep 2020 01:33:31



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 03:16:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 03:16:03

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(18)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	14 Sep 2020 02:31:36
User entered 'Day 18'	System	14 Sep 2020 02:31:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:55:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2a8b53ad-f65c-4040-9005-deeed2972d17'	System	16 Sep 2020 06:55:53
User entered 'Some interference with activity (2)'	System	16 Sep 2020 06:55:53

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(18)

Generated On: 11 Aug 2021 22:47:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:55:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2a8b53ad-f65c-4040-9005-deeed2972d17' User entered '16 Sep 2020 02:55'	System	16 Sep 2020 06:55:53
	System	16 Sep 2020 06:55:53

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 02:31:36

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 02:31:36

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(19)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	15 Sep 2020 01:33:31
User entered 'Day 19'	System	15 Sep 2020 01:33:31



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '37e52a54-a5fe-4907-919d-cb33e0ff2cc6'	System	17 Sep 2020 09:59:40
User entered 'No interference with activity (1)'	System	17 Sep 2020 09:59:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '37e52a54-a5fe-4907-919d-cb33e0ff2cc6' User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:40
	System	17 Sep 2020 09:59:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 01:33:31

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 01:33:31

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(20)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	16 Sep 2020 06:55:53
User entered 'Day 20'	System	16 Sep 2020 06:55:53

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(20)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '706c8dba-c4dd-4fb0-93ea-a9b6731ebf5a'	System	18 Sep 2020 01:52:44
User entered 'Some interference with activity (2)'	System	18 Sep 2020 01:52:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:41', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '706c8dba-c4dd-4fb0-93ea-a9b6731ebf5a' User entered '17 Sep 2020 21:52'	System	18 Sep 2020 01:52:44
	System	18 Sep 2020 01:52:44

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(20)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 06:55:53



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 06:55:53

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(21)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	17 Sep 2020 09:59:40
User entered 'Day 21'	System	17 Sep 2020 09:59:40

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(21)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-18T17:50:32', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4561039d-7088-4eb2-b053-a8a0c682ab8c' User entered 'None (0)'	System	18 Sep 2020 21:50:41
	System	18 Sep 2020 21:50:41

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-18T17:50:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4561039d-7088-4eb2-b053-a8a0c682ab8c' User entered '18 Sep 2020 17:50'	System	18 Sep 2020 21:50:41
	System	18 Sep 2020 21:50:41

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 09:59:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 09:59:40

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 01:13:18
User entered 'Day 8'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '01ae72ad-a182-431b-94ec-bb062f33b901'	System	06 Sep 2020 11:04:31
User entered 'Some interference with activity (2)'	System	06 Sep 2020 11:04:31



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:30', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '01ae72ad-a182-431b-94ec-bb062f33b901' User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:31
	System	06 Sep 2020 11:04:31

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:03:37
User entered 'Day 9'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:07', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '40a4fd72-1d8d-4064-bf7e-36ee9eb57af1'	System	07 Sep 2020 02:12:17
User entered 'Some interference with activity (2)'	System	07 Sep 2020 02:12:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:12', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '40a4fd72-1d8d-4064-bf7e-36ee9eb57af1' User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:17
	System	07 Sep 2020 02:12:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:03:37

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:03:37



US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:04:31
User entered 'Day 10'	System	06 Sep 2020 11:04:31

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:46', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4c9da69e-c75c-4296-b6e2-2db8614e48aa' User entered 'No interference with activity (1)'	System	08 Sep 2020 02:37:56
	System	08 Sep 2020 02:37:56

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4c9da69e-c75c-4296-b6e2-2db8614e48aa' User entered '07 Sep 2020 22:37'	System	08 Sep 2020 02:37:56
	System	08 Sep 2020 02:37:56

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:04:31

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:04:31

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	07 Sep 2020 02:12:17
User entered 'Day 11'	System	07 Sep 2020 02:12:17

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:47:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7681efa4-64df-42aa-8dd8-c324c6767892'	System	09 Sep 2020 01:48:12
User entered 'Some interference with activity (2)'	System	09 Sep 2020 01:48:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:48:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7681efa4-64df-42aa-8dd8-c324c6767892' User entered '08 Sep 2020 21:48'	System	09 Sep 2020 01:48:12
	System	09 Sep 2020 01:48:12



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:12:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:12:17

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	08 Sep 2020 02:37:56
User entered 'Day 12'	System	08 Sep 2020 02:37:56

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(12)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '610e2661-22c6-49e1-8290-ff2d10e5c258' User entered 'None (0)'	System	09 Sep 2020 22:25:40
	System	09 Sep 2020 22:25:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:34', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '610e2661-22c6-49e1-8290-ff2d10e5c258' User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:40
	System	09 Sep 2020 22:25:40

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 02:37:56

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 02:37:56

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 01:13:18
User entered 'Day 8'	System	04 Sep 2020 01:13:18



US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'aaf6bde7-cb17-4832-b65f-24c8a71e1a79'	System	06 Sep 2020 11:04:46
User entered 'No interference with activity (1)'	System	06 Sep 2020 11:04:46

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:41', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'aaf6bde7-cb17-4832-b65f-24c8a71e1a79' User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:46
	System	06 Sep 2020 11:04:46

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:03:37
User entered 'Day 9'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b39552ac-761d-4b1b-a677-0ab4b7e8dc95'	System	07 Sep 2020 02:12:26
User entered 'Some interference with activity (2)'	System	07 Sep 2020 02:12:26

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:24', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b39552ac-761d-4b1b-a677-0ab4b7e8dc95' User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:26
	System	07 Sep 2020 02:12:26

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:03:37



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:04:46
User entered 'Day 10'	System	06 Sep 2020 11:04:46

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:37:59', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '92fecfea-79e4-4a2c-94ab-674ea6cba4fc' User entered 'None (0)'	System	08 Sep 2020 02:38:14
	System	08 Sep 2020 02:38:14

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:38:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '92fecfea-79e4-4a2c-94ab-674ea6cba4fc' User entered '07 Sep 2020 22:38'	System	08 Sep 2020 02:38:14
	System	08 Sep 2020 02:38:14

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:04:46

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:04:46

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 01:13:18
User entered 'Day 8'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'fd15ddec-6fcc-4c90-bc96-040df74bf328'	System	06 Sep 2020 11:04:56
User entered 'No (N)'	System	06 Sep 2020 11:04:56



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T07:04:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'fd15ddec-6fcc-4c90-bc96-040df74bf328'	System	06 Sep 2020 11:04:56
User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:56

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 01:13:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	04 Sep 2020 23:02:19
User entered 'Day 9'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:31', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1d981a5a-53d6-458e-916d-86c6024d91d6' User entered 'No (N)'	System	07 Sep 2020 02:12:48
	System	07 Sep 2020 02:12:48

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-06T22:12:46', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1d981a5a-53d6-458e-916d-86c6024d91d6' User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:48
	System	07 Sep 2020 02:12:48

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 23:02:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 23:02:19



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	06 Sep 2020 11:02:55
User entered 'Day 10'	System	06 Sep 2020 11:02:55

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:38:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2f8d72e9-1b83-474c-97d5-d94face83464' User entered 'No (N)'	System	08 Sep 2020 02:38:19
	System	08 Sep 2020 02:38:19

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:47:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-07T22:38:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2f8d72e9-1b83-474c-97d5-d94face83464' User entered '07 Sep 2020 22:38'	System	08 Sep 2020 02:38:19
	System	08 Sep 2020 02:38:19

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 11:02:55

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 11:02:55

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	07 Sep 2020 02:11:17
User entered 'Day 11'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:48:14', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '12821043-90ba-4e7c-a25b-f43a6e0deeca' User entered 'No (N)'	System	09 Sep 2020 01:48:25
	System	09 Sep 2020 01:48:25

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-08T21:48:21', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '12821043-90ba-4e7c-a25b-f43a6e0deeca'	System	09 Sep 2020 01:48:25
User entered '08 Sep 2020 21:48'	System	09 Sep 2020 01:48:25



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 02:11:17

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	08 Sep 2020 02:37:12
User entered 'Day 12'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f35f97f2-b546-4431-a253-89fe3d92669c' User entered 'No (N)'	System	09 Sep 2020 22:25:42
	System	09 Sep 2020 22:25:42

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-09T18:25:40', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f35f97f2-b546-4431-a253-89fe3d92669c' User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:42
	System	09 Sep 2020 22:25:42

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 02:37:12

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 02:37:12

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 01:46:49
User entered 'Day 13'	System	09 Sep 2020 01:46:49



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b20d0274-63c6-49b1-94ef-075e48659f32'	System	11 Sep 2020 02:20:44
User entered 'No (N)'	System	11 Sep 2020 02:20:44

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-10T22:20:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b20d0274-63c6-49b1-94ef-075e48659f32'	System	11 Sep 2020 02:20:44
User entered '10 Sep 2020 22:20'	System	11 Sep 2020 02:20:44

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:46:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	09 Sep 2020 22:25:17
User entered 'Day 14'	System	09 Sep 2020 22:25:17

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:49:14', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '956dbf16-036a-4edc-b043-b70f2ebe7e68' User entered 'No (N)'	System	11 Sep 2020 19:49:20
	System	11 Sep 2020 19:49:20

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-11T15:49:18', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '956dbf16-036a-4edc-b043-b70f2ebe7e68' User entered '11 Sep 2020 15:49'	System	11 Sep 2020 19:49:20
	System	11 Sep 2020 19:49:20

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 22:25:17



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 22:25:17

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 02:20:22
User entered 'Day 15'	System	11 Sep 2020 02:20:22

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:16:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '004afe91-c648-4e4c-a2b3-6314524fb56d' User entered 'No (N)'	System	13 Sep 2020 03:16:10
	System	13 Sep 2020 03:16:10

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:47:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-12T23:16:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '004afe91-c648-4e4c-a2b3-6314524fb56d' User entered '12 Sep 2020 23:16'	System	13 Sep 2020 03:16:10
	System	13 Sep 2020 03:16:10

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 02:20:22

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 02:20:22

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	11 Sep 2020 19:49:03
User entered 'Day 16'	System	11 Sep 2020 19:49:03

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1bc4f3d1-9c27-40bd-b1da-b02625215af9' User entered 'No (N)'	System	14 Sep 2020 02:31:46
	System	14 Sep 2020 02:31:46



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-13T22:31:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '1bc4f3d1-9c27-40bd-b1da-b02625215af9' User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:46
	System	14 Sep 2020 02:31:46

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:49:03

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:49:03

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	13 Sep 2020 03:15:49
User entered 'Day 17'	System	13 Sep 2020 03:15:49

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:34', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6ef96eb5-3cb3-4ea4-9a5f-94fdcc87fa21' User entered 'No (N)'	System	15 Sep 2020 01:33:39
	System	15 Sep 2020 01:33:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-14T21:33:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6ef96eb5-3cb3-4ea4-9a5f-94fdcc87fa21' User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:39
	System	15 Sep 2020 01:33:39

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 03:15:49

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 03:15:49



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	14 Sep 2020 02:31:27
User entered 'Day 18'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:55:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b6f232af-5c01-4ede-a2ff-b803182dcda0' User entered 'No (N)'	System	16 Sep 2020 06:56:04
	System	16 Sep 2020 06:56:04

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(18)

Generated On: 11 Aug 2021 22:47:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-16T02:56:02', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'b6f232af-5c01-4ede-a2ff-b803182dcda0'	System	16 Sep 2020 06:56:04
User entered '16 Sep 2020 02:56'	System	16 Sep 2020 06:56:04

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 02:31:27

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 02:31:27

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	15 Sep 2020 01:33:18
User entered 'Day 19'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(19)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:45', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c1f8a45e-ad27-49af-b1e2-f7b91a3c6f7b' User entered 'No (N)'	System	17 Sep 2020 09:59:51
	System	17 Sep 2020 09:59:51

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T05:59:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'c1f8a45e-ad27-49af-b1e2-f7b91a3c6f7b' User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:51
	System	17 Sep 2020 09:59:51



**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 01:33:18

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	16 Sep 2020 06:55:34
User entered 'Day 20'	System	16 Sep 2020 06:55:34

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:45', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '718ef1ac-d1b7-4933-96c2-d83ec0375d58' User entered 'No (N)'	System	18 Sep 2020 01:52:52
	System	18 Sep 2020 01:52:52

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-17T21:52:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '718ef1ac-d1b7-4933-96c2-d83ec0375d58'	System	18 Sep 2020 01:52:52
User entered '17 Sep 2020 21:52'	System	18 Sep 2020 01:52:52

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:47:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 06:55:34

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(20)

Generated On: 11 Aug 2021 22:47:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 06:55:34

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:47:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
DataPoint Activated.	System	18 Sep 2020 01:52:44
DataPoint Inactivated.	System	18 Sep 2020 01:52:34
Data entry locked.	System	17 Sep 2020 09:59:30
User entered 'Day 21'	System	17 Sep 2020 09:59:30



US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(21)

Generated On: 11 Aug 2021 22:47:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-18T17:50:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'af0126c1-9933-4372-88d5-465cd82fc081'	System	18 Sep 2020 21:50:52
User entered 'No (N)'	System	18 Sep 2020 21:50:52
DataPoint Activated.	System	18 Sep 2020 01:52:44
DataPoint Inactivated.	System	18 Sep 2020 01:52:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7C087C35-95E7-48FD-9D57-75BFCCFBC2DE)', Time: '2020-09-18T17:50:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'af0126c1-9933-4372-88d5-465cd82fc081'	System	18 Sep 2020 21:50:52
User entered '18 Sep 2020 17:50'	System	18 Sep 2020 21:50:52
DataPoint Activated.	System	18 Sep 2020 01:52:44
DataPoint Inactivated.	System	18 Sep 2020 01:52:34

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
DataPoint Activated.	System	18 Sep 2020 01:52:44
DataPoint Inactivated.	System	18 Sep 2020 01:52:34
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 09:59:30

**US3512176**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 11 Aug 2021 22:47:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
DataPoint Activated.	System	18 Sep 2020 01:52:44
DataPoint Inactivated.	System	18 Sep 2020 01:52:34
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 09:59:30

**US3512176**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:25:29

**US3512176**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '8 Sep 2020'	Sheldon Warren (b) (4)	08 Sep 2020 18:25:29

**US3512176**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:25:29

US3512176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:25:29



US3512176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:25:38

**US3512176**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	08 Sep 2020 18:25:38

**US3512176**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:26:41

**US3512176**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '14 Sep 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:41

**US3512176**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:26:41

**US3512176**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:26:41

US3512176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:26:48

**US3512176**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	14 Sep 2020 17:26:48



**US3512176**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	22 Sep 2020 19:47:03

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 05:12:04
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Added to EDC' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:45:26
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:10:52
User entered '22 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:47:03

**US3512176**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	22 Sep 2020 19:47:03

**US3512176**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	22 Sep 2020 19:47:03

US3512176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	22 Sep 2020 19:47:09

**US3512176**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	22 Sep 2020 19:47:09

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03



US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'VISIT2'	System	05 Nov 2020 15:12:03

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '10:12'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered '30 Sep 2020 10:12'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '98.1' F	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45



US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '78'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'bpm'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '16'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'breaths/min'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '123'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'mmHg'	System	05 Nov 2020 15:13:45



US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '76'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'mmHg'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45



US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:13:45



US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:52

US3512176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:52

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
Query 'Per CDM: Please update the Dosing Discontinuation form as study treatment was not given.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:39:49
User opened query 'Per CDM: Please update the Dosing Discontinuation form as study treatment was not given.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:06:37
Query 'Per CDM: Please update the Dosing dscontinuation form as study treatment is not given.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:05:58
User opened query 'Per CDM: Please update the Dosing dscontinuation form as study treatment is not given.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:05:42
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:15:17



US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55



US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '10:52'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered '30 Sep 2020 10:52'	System	05 Nov 2020 15:15:55

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '10:15'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered '30 Sep 2020 10:15'	System	05 Nov 2020 15:16:18

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18



US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered empty.	System	05 Nov 2020 15:16:18

US3512176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:02:47

**US3512176**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered '1'	System	07 Oct 2020 17:02:47

**US3512176**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '7 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:03:05

**US3512176**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:03:05



US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 17:03:10

**US3512176**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	07 Oct 2020 17:03:10

**US3512176**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:53:25

**US3512176**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '15 Oct 2020'	Sheldon Warren (b) (4)	15 Oct 2020 18:53:25

**US3512176**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:53:25

**US3512176**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:53:25

US3512176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:53:30



**US3512176**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	15 Oct 2020 18:53:30

**US3512176**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:06:07

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:06:07

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Brenda Anderson (b) (4)	05 Nov 2020 15:06:07

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:06:07

US3512176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:06:13

**US3512176**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	05 Nov 2020 15:06:13

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11



US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'VISIT3'	System	05 Nov 2020 15:08:11

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User closed query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 23Oct2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:22:20
Query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 23Oct2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'These vitals do match.' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:34:41
User opened query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 23Oct2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 14:35:09
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '11:53'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '23 Oct 2020 11:53'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '96.9' F	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49



US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '60'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'bpm'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '22'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'breaths/min'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '130'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	05 Nov 2020 15:08:49



US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '81'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'mmHg'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:09

US3512176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:09

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:09:29

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:29



US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '12:05'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:09:29

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered '23 Oct 2020 12:05'	System	05 Nov 2020 15:09:29

US3512176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:34

**US3512176**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 00:01:49
User entered 'I'	System	05 Nov 2020 15:09:34

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 64'	System	29 Aug 2020 13:37:44

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 13:37:44



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 71'	System	29 Aug 2020 13:37:44

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:25:10
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered 'Day 78'	System	29 Aug 2020 13:37:44

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-16T15:44:35', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '34938690-e7dc-48a9-9f6d-0de0ac643a73'	System	16 Nov 2020 20:44:56
User entered 'No (N)'	System	16 Nov 2020 20:44:56

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-16T15:44:41', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '34938690-e7dc-48a9-9f6d-0de0ac643a73'	System	16 Nov 2020 20:44:56
User entered 'No (N)'	System	16 Nov 2020 20:44:56

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-16T15:44:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '34938690-e7dc-48a9-9f6d-0de0ac643a73' User entered '16 Nov 2020 15:44:55'	System	16 Nov 2020 20:44:56
	System	16 Nov 2020 20:44:56



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:19:11
Data entry locked.	System	29 Aug 2020 13:37:44
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 13:37:44

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-19T18:23:20', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7803d641-50d3-4ffc-8e03-cfa9c95270cb' User entered 'No (N)'	System	19 Nov 2020 23:23:39

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-19T18:23:26', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7803d641-50d3-4ffc-8e03-cfa9c95270cb' User entered 'No (N)'	System	19 Nov 2020 23:23:39

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-19T18:23:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '7803d641-50d3-4ffc-8e03-cfa9c95270cb' User entered '19 Nov 2020 18:23:37'	System	19 Nov 2020 23:23:39
	System	19 Nov 2020 23:23:39

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:25:10



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-23T04:05:39', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '90b7a771-3e73-4890-ad99-25423aab49f1' User entered 'No (N)'	System	23 Nov 2020 09:06:16
	System	23 Nov 2020 09:06:16

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-23T04:06:03', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '90b7a771-3e73-4890-ad99-25423aab49f1'	System	23 Nov 2020 09:06:16
User entered 'No (N)'	System	23 Nov 2020 09:06:16

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-23T04:06:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '90b7a771-3e73-4890-ad99-25423aab49f1'	System	23 Nov 2020 09:06:16
User entered '23 Nov 2020 04:06:13'	System	23 Nov 2020 09:06:16

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:25:10

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-30T18:29:37', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a9a96f12-cac1-4624-ae6e-16d3c3af8aba' User entered 'No (N)'	System	30 Nov 2020 23:30:10
	System	30 Nov 2020 23:30:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-30T18:29:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a9a96f12-cac1-4624-ae6e-16d3c3af8aba' User entered 'No (N)'	System	30 Nov 2020 23:30:10
	System	30 Nov 2020 23:30:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-11-30T18:30:08', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'a9a96f12-cac1-4624-ae6e-16d3c3af8aba' User entered '30 Nov 2020 18:30:08'	System	30 Nov 2020 23:30:10
	System	30 Nov 2020 23:30:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:25:10

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:25:10

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-07T06:42:25', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0ed125b-f0f4-40d0-bbc2-b93d3034302d' User entered 'Yes (Y)'	System	07 Dec 2020 11:43:11
	System	07 Dec 2020 11:43:11

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-07T06:42:32', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0ed125b-f0f4-40d0-bbc2-b93d3034302d' User entered 'No (N)'	System	07 Dec 2020 11:43:11
	System	07 Dec 2020 11:43:11

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-07T06:42:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0ed125b-f0f4-40d0-bbc2-b93d3034302d' User entered 'No (N)'	System	07 Dec 2020 11:43:11
	System	07 Dec 2020 11:43:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-07T06:42:50', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0ed125b-f0f4-40d0-bbc2-b93d3034302d' User entered 'No (N)'	System	07 Dec 2020 11:43:11
	System	07 Dec 2020 11:43:11

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-07T06:43:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0ed125b-f0f4-40d0-bbc2-b93d3034302d' User entered '07 Dec 2020 06:43:09'	System	07 Dec 2020 11:43:11
	System	07 Dec 2020 11:43:11

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-14T00:48:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd44b7361-6882-4068-9470-fb181ec39cbc' User entered 'Yes (Y)'	System	14 Dec 2020 06:58:18
	System	14 Dec 2020 06:58:18

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-14T00:49:01', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd44b7361-6882-4068-9470-fb181ec39cbc'	System	14 Dec 2020 06:58:18
User entered 'No (N)'	System	14 Dec 2020 06:58:18

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-14T00:49:13', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd44b7361-6882-4068-9470-fb181ec39cbc'	System	14 Dec 2020 06:58:18
User entered 'No (N)'	System	14 Dec 2020 06:58:18



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-14T01:57:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd44b7361-6882-4068-9470-fb181ec39cbc'	System	14 Dec 2020 06:58:18
User entered 'No (N)'	System	14 Dec 2020 06:58:18

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-14T01:58:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd44b7361-6882-4068-9470-fb181ec39cbc' User entered '14 Dec 2020 01:58:15'	System	14 Dec 2020 06:58:18
	System	14 Dec 2020 06:58:18

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-21T00:38:15', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0b1479a2-d607-49aa-b668-181a3bbef700'	System	21 Dec 2020 05:41:05
User entered 'No (N)'	System	21 Dec 2020 05:41:05

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-21T00:38:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0b1479a2-d607-49aa-b668-181a3bbef700'	System	21 Dec 2020 05:41:05
User entered 'No (N)'	System	21 Dec 2020 05:41:05

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-21T00:41:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0b1479a2-d607-49aa-b668-181a3bbef700' User entered '21 Dec 2020 00:41:00'	System	21 Dec 2020 05:41:05
	System	21 Dec 2020 05:41:05



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-28T02:52:53', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b2aa62d-fc0f-4506-a5c6-a1c206251f6a'	System	28 Dec 2020 07:53:38
User entered 'Yes (Y)'	System	28 Dec 2020 07:53:38

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-28T02:53:06', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b2aa62d-fc0f-4506-a5c6-a1c206251f6a' User entered 'No (N)'	System	28 Dec 2020 07:53:38
	System	28 Dec 2020 07:53:38

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-28T02:53:14', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b2aa62d-fc0f-4506-a5c6-a1c206251f6a' User entered 'No (N)'	System	28 Dec 2020 07:53:38
	System	28 Dec 2020 07:53:38

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-28T02:53:23', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b2aa62d-fc0f-4506-a5c6-a1c206251f6a' User entered 'No (N)'	System	28 Dec 2020 07:53:38
	System	28 Dec 2020 07:53:38

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2020-12-28T02:53:36', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b2aa62d-fc0f-4506-a5c6-a1c206251f6a' User entered '28 Dec 2020 02:53:36'	System	28 Dec 2020 07:53:38
	System	28 Dec 2020 07:53:38



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-04T04:29:42', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6c2d8d11-ef44-477b-864d-4fe0d7cfb5df' User entered 'Yes (Y)'	System	04 Jan 2021 09:30:58
	System	04 Jan 2021 09:30:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-04T04:29:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6c2d8d11-ef44-477b-864d-4fe0d7cfb5df'	System	04 Jan 2021 09:30:58
User entered 'No (N)'	System	04 Jan 2021 09:30:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-04T04:30:09', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6c2d8d11-ef44-477b-864d-4fe0d7cfb5df' User entered 'No (N)'	System	04 Jan 2021 09:30:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-04T04:30:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6c2d8d11-ef44-477b-864d-4fe0d7cfb5df'	System	04 Jan 2021 09:30:58
User entered 'No (N)'	System	04 Jan 2021 09:30:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-04T04:30:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '6c2d8d11-ef44-477b-864d-4fe0d7cfb5df' User entered '04 Jan 2021 04:30:55'	System	04 Jan 2021 09:30:58
	System	04 Jan 2021 09:30:58



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-11T03:31:44', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '83992648-6673-461d-b491-0a7434b769c7'	System	11 Jan 2021 08:32:09
User entered 'No (N)'	System	11 Jan 2021 08:32:09

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-11T03:31:49', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '83992648-6673-461d-b491-0a7434b769c7'	System	11 Jan 2021 08:32:09
User entered 'No (N)'	System	11 Jan 2021 08:32:09

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BD1B2773-205F-4D44-AF57-BC0139C99B45)', Time: '2021-01-11T03:32:04', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '83992648-6673-461d-b491-0a7434b769c7' User entered '11 Jan 2021 03:32:04'	System	11 Jan 2021 08:32:09

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-22T11:28:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'af9f52be-ff14-4e01-b717-1595d5f89b41' User entered 'No (N)'	System	22 Jan 2021 16:28:56
	System	22 Jan 2021 16:28:56

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-22T11:28:45', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'af9f52be-ff14-4e01-b717-1595d5f89b41' User entered 'No (N)'	System	22 Jan 2021 16:28:56
	System	22 Jan 2021 16:28:56

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-22T11:28:54', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'af9f52be-ff14-4e01-b717-1595d5f89b41' User entered '22 Jan 2021 11:28:54'	System	22 Jan 2021 16:28:56
	System	22 Jan 2021 16:28:56

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-25T03:43:33', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4feddea0-a4ef-4ae3-8bc4-6b26499e3529'	System	25 Jan 2021 08:43:58
User entered 'No (N)'	System	25 Jan 2021 08:43:58



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-25T03:43:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4feddea0-a4ef-4ae3-8bc4-6b26499e3529'	System	25 Jan 2021 08:43:58
User entered 'No (N)'	System	25 Jan 2021 08:43:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-01-25T03:43:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4feddea0-a4ef-4ae3-8bc4-6b26499e3529' User entered '25 Jan 2021 03:43:56'	System	25 Jan 2021 08:43:58

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-03T09:17:56', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cd8b5c4e-b759-42b4-b24b-a22535a70b88'	System	03 Feb 2021 14:18:34
User entered 'No (N)'	System	03 Feb 2021 14:18:34

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-03T09:18:17', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cd8b5c4e-b759-42b4-b24b-a22535a70b88'	System	03 Feb 2021 14:18:34
User entered 'No (N)'	System	03 Feb 2021 14:18:34

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-03T09:18:28', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'cd8b5c4e-b759-42b4-b24b-a22535a70b88'	System	03 Feb 2021 14:18:34
User entered '03 Feb 2021 09:18:28'	System	03 Feb 2021 14:18:34



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-08T06:52:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '945ccd1c-ff32-47e2-8c16-04887e03241c' User entered 'No (N)'	System	08 Feb 2021 11:53:10
	System	08 Feb 2021 11:53:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-08T06:52:55', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '945ccd1c-ff32-47e2-8c16-04887e03241c'	System	08 Feb 2021 11:53:10
User entered 'No (N)'	System	08 Feb 2021 11:53:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-08T06:53:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '945ccd1c-ff32-47e2-8c16-04887e03241c' User entered '08 Feb 2021 06:53:00'	System	08 Feb 2021 11:53:10
	System	08 Feb 2021 11:53:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-15T17:16:19', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ac40a1ea-57b6-4bf4-ba8a-cdec5a50f387'	System	15 Feb 2021 22:16:35
User entered 'No (N)'	System	15 Feb 2021 22:16:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-15T17:16:22', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ac40a1ea-57b6-4bf4-ba8a-cdec5a50f387'	System	15 Feb 2021 22:16:35
User entered 'No (N)'	System	15 Feb 2021 22:16:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-15T17:16:29', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'ac40a1ea-57b6-4bf4-ba8a-cdec5a50f387' User entered '15 Feb 2021 17:16:29'	System	15 Feb 2021 22:16:35
	System	15 Feb 2021 22:16:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-22T04:05:38', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4e8e1cf8-0796-43b2-a8a9-74edffbb46b1' User entered 'No (N)'	System	22 Feb 2021 09:05:52
	System	22 Feb 2021 09:05:52



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-22T04:05:43', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4e8e1cf8-0796-43b2-a8a9-74edffbb46b1' User entered 'No (N)'	System	22 Feb 2021 09:05:52

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-02-22T04:05:48', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '4e8e1cf8-0796-43b2-a8a9-74edffbb46b1' User entered '22 Feb 2021 04:05:48'	System	22 Feb 2021 09:05:52

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-01T02:18:40-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'eba7a952-b3bf-4961-be59-891b392aeb77'	System	01 Mar 2021 07:19:10
User entered 'No (N)'	System	01 Mar 2021 07:19:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-01T02:18:58-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'eba7a952-b3bf-4961-be59-891b392aeb77'	System	01 Mar 2021 07:19:10
User entered 'No (N)'	System	01 Mar 2021 07:19:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-01T02:19:07-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'eba7a952-b3bf-4961-be59-891b392aeb77'	System	01 Mar 2021 07:19:10
User entered '01 Mar 2021 07:19:07'	System	01 Mar 2021 07:19:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-08T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '62ba9ffc-06e3-48d1-bfab-db479438e114'	System	08 Mar 2021 05:04:14
User entered 'No (N)'	System	08 Mar 2021 05:04:14

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-08T00:02:54-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '62ba9ffc-06e3-48d1-bfab-db479438e114'	System	08 Mar 2021 05:04:14
User entered 'No (N)'	System	08 Mar 2021 05:04:14

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-08T00:02:59-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '62ba9ffc-06e3-48d1-bfab-db479438e114'	System	08 Mar 2021 05:04:14
User entered '08 Mar 2021 00:02:59'	System	08 Mar 2021 05:04:14

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-18T18:01:35-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd89b4c6f-f32a-44b6-b5a0-3c1046d139d8'	System	18 Mar 2021 22:05:35
User entered 'No (N)'	System	18 Mar 2021 22:05:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-18T18:01:39-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd89b4c6f-f32a-44b6-b5a0-3c1046d139d8'	System	18 Mar 2021 22:05:35
User entered 'No (N)'	System	18 Mar 2021 22:05:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-18T18:01:47-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd89b4c6f-f32a-44b6-b5a0-3c1046d139d8'	System	18 Mar 2021 22:05:35
User entered '18 Mar 2021 18:01:47'	System	18 Mar 2021 22:05:35

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-24T12:33:21-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45e630f-74a7-4551-a624-7e332b81904d'	System	24 Mar 2021 16:33:34
User entered 'No (N)'	System	24 Mar 2021 16:33:34



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-24T12:33:26-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45e630f-74a7-4551-a624-7e332b81904d'	System	24 Mar 2021 16:33:34
User entered 'No (N)'	System	24 Mar 2021 16:33:34

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-24T12:33:29-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'd45e630f-74a7-4551-a624-7e332b81904d' User entered '24 Mar 2021 12:33:29'	System	24 Mar 2021 16:33:34
	System	24 Mar 2021 16:33:34

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-31T08:48:10-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0cecf706-19c0-4f82-a935-82fd8ab749e4'	System	31 Mar 2021 12:48:23
User entered 'No (N)'	System	31 Mar 2021 12:48:23

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-31T08:48:13-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0cecf706-19c0-4f82-a935-82fd8ab749e4'	System	31 Mar 2021 12:48:23
User entered 'No (N)'	System	31 Mar 2021 12:48:23

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-31T08:48:21-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '0cecf706-19c0-4f82-a935-82fd8ab749e4'	System	31 Mar 2021 12:48:23
User entered '31 Mar 2021 08:48:21'	System	31 Mar 2021 12:48:23



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-05T05:59:16-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2fec8938-d2b8-45d0-bd14-0dd166fe42cb'	System	09 Apr 2021 20:13:08
User entered 'No (N)'	System	09 Apr 2021 20:13:08

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-05T05:59:21-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2fec8938-d2b8-45d0-bd14-0dd166fe42cb'	System	09 Apr 2021 20:13:08
User entered 'No (N)'	System	09 Apr 2021 20:13:08

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-05T05:59:24-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '2fec8938-d2b8-45d0-bd14-0dd166fe42cb' User entered '05 Apr 2021 05:59:24'	System	09 Apr 2021 20:13:08
	System	09 Apr 2021 20:13:08

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-12T00:22:30-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f3e94212-aaa4-4d66-bbc4-a11f58919a74' User entered 'No (N)'	System	12 Apr 2021 04:22:44

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-12T00:22:38-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f3e94212-aaa4-4d66-bbc4-a11f58919a74'	System	12 Apr 2021 04:22:44
User entered 'No (N)'	System	12 Apr 2021 04:22:44

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-12T00:22:42-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'f3e94212-aaa4-4d66-bbc4-a11f58919a74'	System	12 Apr 2021 04:22:44
User entered '12 Apr 2021 00:22:42'	System	12 Apr 2021 04:22:44

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-19T08:07:45-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b60a941-e594-458a-9f3f-f0e6641bb49c'	System	19 Apr 2021 12:08:20
User entered 'No (N)'	System	19 Apr 2021 12:08:20



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-19T08:08:08-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b60a941-e594-458a-9f3f-f0e6641bb49c'	System	19 Apr 2021 12:08:20
User entered 'No (N)'	System	19 Apr 2021 12:08:20

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-19T08:08:17-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '8b60a941-e594-458a-9f3f-f0e6641bb49c'	System	19 Apr 2021 12:08:20
User entered '19 Apr 2021 08:08:17'	System	19 Apr 2021 12:08:20

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-26T00:31:10-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '045fe570-9bcd-46ca-bd3f-f1b611e74008'	System	26 Apr 2021 04:31:53
User entered 'No (N)'	System	26 Apr 2021 04:31:53

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-26T00:31:21-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '045fe570-9bcd-46ca-bd3f-f1b611e74008'	System	26 Apr 2021 04:31:53
User entered 'No (N)'	System	26 Apr 2021 04:31:53

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-04-26T00:31:48-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: '045fe570-9bcd-46ca-bd3f-f1b611e74008'	System	26 Apr 2021 04:31:53
User entered '26 Apr 2021 00:31:48'	System	26 Apr 2021 04:31:53



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-05-03T22:45:56-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'dae63d69-88d5-44e6-807e-0ca814737a8c'	System	04 May 2021 02:46:15
User entered 'No (N)'	System	04 May 2021 02:46:15

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-05-03T22:46:02-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'dae63d69-88d5-44e6-807e-0ca814737a8c'	System	04 May 2021 02:46:15
User entered 'No (N)'	System	04 May 2021 02:46:15

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-05-03T22:46:07-04:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'dae63d69-88d5-44e6-807e-0ca814737a8c'	System	04 May 2021 02:46:15
User entered '03 May 2021 22:46:07'	System	04 May 2021 02:46:15

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:25:10



**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:25:10

**US3512176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:25:10

US3512176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:47:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-01T02:17:55-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0f4df28-1f21-44dd-80fb-ba6bafa2113e'	System	01 Mar 2021 07:18:13
User entered 'No (N)'	System	01 Mar 2021 07:18:13

**US3512176**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:39:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FF8609C-80EF-4AAC-923A-D933268690D9)', Time: '2021-03-01T02:18:10-05:00', User OID: 'PatientReportedOutcome (US3512176)', ODM File OID: 'e0f4df28-1f21-44dd-80fb-ba6bafa2113e'	System	01 Mar 2021 07:18:13
User entered '01 Mar 2021 07:18:10'	System	01 Mar 2021 07:18:13

**US3512176**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Nov 2020 18:58:57

**US3512176**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '23 Nov 2020'	Sheldon Warren (b) (4)	23 Nov 2020 18:58:57

**US3512176**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	23 Nov 2020 18:58:57

US3512176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Sheldon Warren (b) (4)	23 Nov 2020 18:58:57



US3512176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Nov 2020 18:59:01

**US3512176**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:37:30
User entered 'I'	System	23 Nov 2020 18:59:01

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	28 Dec 2020 19:50:18

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '28 Dec 2020'	Sheldon Warren (b) (4)	28 Dec 2020 19:50:18

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 19:50:18

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 19:50:18

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Dec 2020 19:50:24

**US3512176**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered '1'	System	28 Dec 2020 19:50:24



**US3512176**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Jan 2021 19:11:09

**US3512176**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '26 Jan 2021'	Sheldon Warren (b) (4)	26 Jan 2021 19:11:09

**US3512176**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	26 Jan 2021 19:11:09

US3512176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	26 Jan 2021 19:11:09

**US3512176**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Jan 2021 19:11:15

**US3512176**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered 'I'	System	26 Jan 2021 19:11:15

**US3512176**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:59:43
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	25 Feb 2021 14:40:20

**US3512176**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:59:43
User entered '25 Feb 2021'	(b) (4) Taylor Johnson (b) (4)	25 Feb 2021 14:40:20



**US3512176**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:59:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	25 Feb 2021 14:40:20

US3512176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:59:43
User entered empty.	(b) (4) Taylor Johnson (b) (4)	25 Feb 2021 14:40:20

**US3512176**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:59:43
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	25 Feb 2021 14:40:26

**US3512176**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered 'I'	System	25 Feb 2021 14:40:26

US3512176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:01

US3512176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:01

US3512176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:01

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered 'VISIT4'	System	31 Mar 2021 21:55:01



US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered empty.	System	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53



**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered empty.	System	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered empty.	System	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered empty.	System	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:53

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered empty.	System	31 Mar 2021 21:54:53

US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41



US3512176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41

US3512176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:47

US3512176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:54:47

US3512176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:19

US3512176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:19

US3512176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered '10:26'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:19

**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered '31 Mar 2021 10:26'	System	31 Mar 2021 21:54:19

US3512176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:54:07



**US3512176**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:59:41
User entered 'I'	System	31 Mar 2021 21:54:07

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:34
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 20:11:52
	(b) (4)	

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:34
	(b) (4)	
User entered '26 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 20:11:52
	(b) (4)	

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:34
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	26 Apr 2021 20:11:52
	(b) (4)	

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:34
User entered empty.	(b) (4) Sheldon Warren (b) (4)	26 Apr 2021 20:11:52
	(b) (4)	

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:34
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 20:11:58
	(b) (4)	

**US3512176**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 20:11:58

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:15
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:12:24
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	19 Nov 2020 13:33:50
User entered '23 Oct 2020'	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05
	(b) (4)	



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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:15
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:12:24
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 13:33:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:33:58
User entered '09:06' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:33:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 14:45:05
User entered empty.	System	05 Nov 2020 14:45:05
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:15
User entered '22 Oct 2020 09:06'	System	19 Nov 2020 13:33:58
User entered empty.	System	05 Nov 2020 14:45:05

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:15
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:12:24
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:15
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:12:24
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 1 (Day 1)'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
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	05 Nov 2020 14:49:10
User entered '23 Oct 2020' reason for change: Data Entry Error	System	05 Nov 2020 14:49:10
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	(b) (4)	
	System	05 Nov 2020 14:45:47
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:45:47

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:50:43
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User entered '%'	System	05 Nov 2020 14:50:43
User entered empty.	System	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96.9' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:50:43
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	



US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 2 (Day 2)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '24 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User entered '%'	System	05 Nov 2020 14:54:27
User entered empty.	System	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
	(b) (4)	05 Nov 2020 14:49:10



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '25 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	05 Nov 2020 15:14:56
User entered '97.' (non-conformant).	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User entered '%'	System	05 Nov 2020 15:14:56
User entered empty.	System	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



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Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
	(b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 4 (Day 4)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '26 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
User entered '%'	System	05 Nov 2020 14:54:27
User entered empty.	System	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97.4' F reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10



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Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
	(b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:52:45



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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

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Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:22
User entered '0'	System	05 Nov 2020 14:52:45

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Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:47:58

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	01 Feb 2021 15:43:20
User entered 'No (N)'	(b) (4)	
	Brenda Anderson (b) (4)	05 Nov 2020 15:02:23
	(b) (4)	

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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:29
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:46:13



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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:29
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '08:40'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:46:13

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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:29
User entered '27 Jan 2021 08:40'	System	01 Feb 2021 15:46:13

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:58

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:29
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:46:13

**US3512176**

**Folder: Covid-19 Assessment 27 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:58**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:29
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	01 Feb 2021 15:46:13

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 1 (Day 1)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '25 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96.7' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 2 (Day 2)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97.8' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Moderate (Moderate)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98.3' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Moderate (Moderate)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 4 (Day 4)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '28 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96.6' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 5 (Day 5)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '29 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '99'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97.4' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Day 6 (Day 6)'	Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '30 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '97'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
User entered '%'	System	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98.0' F	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:52:47

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Folder: Covid-19 Assessment 27 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:52:47



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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:54:28

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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Feb 2021 19:20:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 19:20:45
User entered 'No (N)' reason for change: New Information	Brenda Anderson (b) (4)	01 Feb 2021 19:20:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Feb 2021 15:54:28
User entered empty.	System	01 Feb 2021 15:54:28
	Brenda Anderson (b) (4)	01 Feb 2021 15:54:28
	(b) (4)	

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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:54:28



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Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:15:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:54:28

US3512176

Folder: Covid-19 Assessment 27 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:58

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:36
User entered '0'	System	01 Feb 2021 15:54:28

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:34:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:34:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:34:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:05:09
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '25 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:34:46
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	



US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	



**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

**US3512176**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

US3512176

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53
	(b) (4)	



**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

US3512176

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:58

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:23:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SEE REPORT DATED 06FEB2021 ACCESSION #1F60DIE. DATA CONFIRMED AS IS.' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	14 Feb 2021 19:17:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 06:25:50
User entered '29 Jan 2021'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

US3512176

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

US3512176

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:58

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53



**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53



**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

**US3512176**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:34
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:53

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:46:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'Added to EDC' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:35:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:31:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:55:24

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:55:24

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Clinic (Clinic)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:55:24

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'SICKD1'	System	05 Nov 2020 14:55:24



US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '11:56'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered '23 Oct 2020 11:56'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '60.25' in	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
DataPoint set to visible.	(b) (4) System	05 Nov 2020 14:55:24

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96.1' kg	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
DataPoint set to visible.	(b) (4) System	05 Nov 2020 14:55:24

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '96.9' F	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:01:17

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17



**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '60'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'bpm'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '22'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'breaths/min'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '130'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'mmHg'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '81'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17



US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'mmHg'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:28

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:01:28

US3512176

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:58

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:45

US3512176

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '23 Oct 2020'	(b) (4) Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:45

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:55:49



**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:55:49

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:46
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Clinic (Clinic)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:55:49

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'SICKD1'	System	01 Feb 2021 15:55:49

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '08:57'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered '27 Jan 2021 08:57'	System	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '60.3' in	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:57:15
DataPoint set to visible.	(b) (4) System	01 Feb 2021 15:55:49



US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered missing code ND - Not Done.	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:57:15
DataPoint set to visible.	(b) (4) System	01 Feb 2021 15:55:49

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '98.3' F	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '63'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'bpm'	System	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '12'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'breaths/min'	System	01 Feb 2021 15:57:15



US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 04:13:40
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'NCS, not an AE' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 16:09:22
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:07:44
User entered '155'	Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'mmHg'	System	01 Feb 2021 15:57:15

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '85'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
User entered 'mmHg'	System	01 Feb 2021 15:57:15

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:26

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:16:59
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:26



US3512176

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:58

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:17:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	01 Feb 2021 15:57:35

**US3512176**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:17:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '27 Jan 2021'	(b) (4) Brenda Anderson (b) (4) (b) (4)	01 Feb 2021 15:57:35

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:02:48
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:02:48
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:02:48
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	05 Nov 2020 15:02:48

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	



**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	



**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:02
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:03:07
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:07
	(b) (4)	

US3512176

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:58**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:03:12
	(b) (4)	



US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:58

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:12
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Feb 2021 15:57:54
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:57:54
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:57:54
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Feb 2021 15:57:54

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	



**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 15:58:00

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 15:58:00

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 15:58:00



US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 15:58:00

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:00
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 15:58:00

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:05
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:05
	(b) (4)	

US3512176

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:58**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	01 Feb 2021 15:58:10
	(b) (4)	

**US3512176**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:58**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	01 Feb 2021 15:58:10
	(b) (4)	



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 17:57:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 17:57:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	03 Feb 2021 17:57:56

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 17:57:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:58**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:18:38

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:58**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:18:38



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Placebo (Placebo)'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Placebo (Placebo)'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Not Administered (NA)'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 17:58:56

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:58**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '1'	System	03 Feb 2021 17:58:56

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'I'	System	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '60.25' in	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '209.4' lb	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '40.64176'	System	03 Feb 2021 18:01:10
DataPoint set to visible.	System	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '60.25' in	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '209.4' lb	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '40.64176'	System	03 Feb 2021 18:01:10
DataPoint set to visible.	System	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '09:55'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Feb 2021 09:55'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '97.2' F	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '56'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'bpm'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '14'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'breaths/min'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '154'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '87'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '60.25' in	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '209.4' lb	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '40.64176'	System	03 Feb 2021 18:01:10
DataPoint set to visible.	System	03 Feb 2021 17:58:56



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '11:24'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Feb 2021 11:24'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '97.1' F	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '58'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'bpm'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '16'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'breaths/min'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '152'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '90'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:10

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Feb 2021 18:01:10



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:53

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:01:53

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26

US3512176

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mRNA-1273'	System	03 Feb 2021 18:02:26
DataPoint set to visible.	System	03 Feb 2021 17:58:56

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '10:50'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Feb 2021 10:50'	System	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'ONCE'	System	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 18:02:26

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:47

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:47

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '09:40'	Brenda Anderson (b) (4)	03 Feb 2021 18:02:47

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Feb 2021 09:40'	System	03 Feb 2021 18:02:47



US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:03:05

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '3 Feb 2021'	Brenda Anderson (b) (4)	03 Feb 2021 18:03:05

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '09:35'	Brenda Anderson (b) (4)	03 Feb 2021 18:03:05

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:47:58**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Feb 2021 09:35'	System	03 Feb 2021 18:03:05

US3512176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Feb 2021 18:03:11

**US3512176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'I'	System	03 Feb 2021 18:03:11

**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 20:18:34

**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '10 Feb 2021'	Sheldon Warren (b) (4)	10 Feb 2021 20:18:34



**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	10 Feb 2021 20:18:34

US3512176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 20:18:34

**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	10 Feb 2021 20:18:46

**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'I'	System	10 Feb 2021 20:18:46

**US3512176**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '1'	System	10 Feb 2021 20:18:46
DataPoint set to visible.	System	10 Feb 2021 20:18:46

**US3512176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:09:08

**US3512176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 16:09:08

**US3512176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	03 Mar 2021 16:09:08



**US3512176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'OLD29'	System	03 Mar 2021 16:09:08

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '09:19'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Mar 2021 09:19'	System	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '98.1' F	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23



**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '73'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'bpm'	System	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '15'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'breaths/min'	System	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '125'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '79'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23



**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '10:45'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Mar 2021 10:45'	System	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '98.7' F	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23



**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '61'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'bpm'	System	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '14'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'breaths/min'	System	03 Mar 2021 16:10:23

US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '150'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '96'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:23



US3512176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mmHg'	System	03 Mar 2021 16:10:23

**US3512176**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:31

US3512176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:31

**US3512176**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56

**US3512176**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'mRNA-1273'	System	03 Mar 2021 16:10:56
DataPoint set to visible.	System	10 Feb 2021 20:18:46

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56



US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered '10:12'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56

**US3512176**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered '3 Mar 2021 10:12'	System	03 Mar 2021 16:10:56

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	03 Mar 2021 16:10:56

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'ONCE'	System	03 Mar 2021 16:10:56

US3512176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 16:10:56

**US3512176**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:42:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 16:11:01

**US3512176**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'I'	System	03 Mar 2021 16:11:01

**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:26:57



**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered '12 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:26:57

**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:26:57

**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:26:57

**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:49:33
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:26:48

**US3512176**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:04
User entered 'I'	System	12 Mar 2021 20:26:48

**US3512176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:17
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:17
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:17
	(b) (4)	



**US3512176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:58**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 21:55:17

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	02 Apr 2021 19:29:03
User entered empty.	Brenda Anderson (b) (4) (b) (4)	31 Mar 2021 21:55:29

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:55:29

US3512176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	



**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:55:29

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:55:29

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:55:29

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:29
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:55:29



**US3512176**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:32
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:55:32
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:46
	(b) (4)	

US3512176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:46
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '10:26'	Brenda Anderson (b) (4)	31 Mar 2021 21:55:46
	(b) (4)	

**US3512176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:26'	System	31 Mar 2021 21:55:46

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:47:58

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'I'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54



**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'I'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: **Unscheduled 25 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:47:58**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: **Unscheduled 25 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:47:58**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '10:59'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User entered '25 Sep 2020 10:59'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '98.7' F	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54



US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '65'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User entered 'bpm'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '12'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User entered 'breaths/min'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '118'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User entered 'mmHg'	System	05 Nov 2020 15:40:54



US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '77'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54

**US3512176**

**Folder: Unscheduled 25 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44
User entered 'mmHg'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 23:56:44

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:44

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 15:41:06

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:56:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:27:33
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:41:06

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:47:58**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:11
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:20:45

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:34:12
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'patient was not brought in for swab, as sub-I determined this vaccine related. Source will have documentation' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:12:21
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:21:37
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:56:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:56:28
Data point term sent to Coder	System	04 Feb 2021 22:55:45
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:55:30
User entered 'worsening HEADACHE' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:55:30



US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:23:58
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'data confirmed as is. please note this is related to IP and is considered a solicited AR' (Site from DM).	Taylor Johnson (b) (4)	23 Dec 2020 20:43:22
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:14:10
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:29:54
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'Solicited AR, per investigator related to investigation IP, No illness visit visit required.' (Site from DM).	Sheldon Warren (b) (4)	07 Oct 2020 16:47:09

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:45:27
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:24:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:24:44
Data point term sent to Coder	System	14 Sep 2020 17:23:12
User entered 'headache'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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	14 Sep 2020 17:22:46
User entered 'No (N)' reason for change: Per Query Resolution	System	14 Sep 2020 17:22:46
User entered 'No (N)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	14 Sep 2020 17:22:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Sep 2020 17:22:17
	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '31 Aug 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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).	(b) (4)	14 Sep 2020 17:22:46
User entered empty; reason for change Per Query Resolution	Sheldon Warren (b) (4)	14 Sep 2020 17:22:46
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	14 Sep 2020 17:22:17
User entered '7:15'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:22:46
User entered '31 Aug 2020 7:15'	System	14 Sep 2020 17:22:17



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '20 Sep 2020' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:22:17

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 05:18:01
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'per query only 1 AE can be used' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	03 Feb 2021 18:16:20
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:09:40
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:56:51
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	14 Dec 2020 19:17:31
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:15:19

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank You for the response, however please note that there are several AEs recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:03:19
Query 'Per CDM: Thank You for the response, however please note that there are several AEs recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' answered with 'They are both considered primary per investigator. Please speak with monitor.' (Site from DM).	Allison Crain (b) (4) (b) (4)	02 Dec 2020 21:02:40
User opened query 'Per CDM: Thank You for the response, however please note that there are several AEs recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:17:06
User closed query 'Per CDM: Only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:17:06
Query 'Per CDM: Only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' answered with 'The site cannot find anywhere in the guidelines that this is the requirement. Both AE's together are the primary and accurate cause of Dosing Discontinuation. Please contact monitor with any further questions.' (Site from DM).	Allison Crain (b) (4) (b) (4)	27 Nov 2020 18:43:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:03:36
User closed query 'Per CDM: it appears there are several records with IP WITHDRAWN. Please consider the primary cause of dose discontinuation and make ALL appropriate updates. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:03:36
Query 'Per CDM: it appears there are several records with IP WITHDRAWN. Please consider the primary cause of dose discontinuation and make ALL appropriate updates. ' answered with 'The primary reason for withdraw of IP was both AEs of "intermittent hives on neck and face" though AEs of headache and fatigue also informed the investigator and subjects decision to withdraw IP. Data confirmed as is.' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	25 Nov 2020 15:35:19
User opened query 'Per CDM: it appears there are several records with IP WITHDRAWN. Please consider the primary cause of dose discontinuation and make ALL appropriate updates. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:27:00
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 20:44:03
User entered 'None (NONE)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
Signature has been broken.	Allison Crain (b) (4)	09 Apr 2021 13:05:02
	(b) (4)	
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'I'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:22:17

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:22:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
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)	19 Feb 2021 21:25:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 21:25:59
Data point term sent to Coder	System	19 Feb 2021 21:24:53
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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)	04 Feb 2021 22:22:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 22:22:33
Data point term sent to Coder	System	04 Feb 2021 22:21:20
Coding entries removed.	Brenda Anderson (b) (4)	04 Feb 2021 22:20:22
User entered 'intermittent FATIGUE' reason for change: New Information	Brenda Anderson (b) (4)	04 Feb 2021 22:20:22
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:30:02
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' 'answered with 'Solicited AR, per investigator related to investigation IP, No illness visit visit required.' (Site from DM).	Sheldon Warren (b) (4)	07 Oct 2020 16:47:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:45:35
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) (b) (4)	14 Sep 2020 17:24:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:24:45
Data point term sent to Coder	System	14 Sep 2020 17:24:18
User entered 'Fatigue'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '30 Aug 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '10:00'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 10:00'	System	14 Sep 2020 17:23:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Brenda Anderson (b) (4)	25 Nov 2020 15:17:30
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '07 Jan 2021' reason for change: New Information	Brenda Anderson (b) (4)	04 Feb 2021 22:20:22
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:18:26
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Nov 2020 15:18:26
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:17:30
User entered '18 Sep 2020' reason for change: New Information	Brenda Anderson (b) (4)	25 Nov 2020 15:17:30
	(b) (4)	
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
	(b) (4)	
User entered '18 Sep 2020' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 17:24:01
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 17:24:01
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 17:23:42
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 15:18:03
User entered '10:00' reason for change: New Information	Brenda Anderson (b) (4)	25 Nov 2020 15:18:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Nov 2020 15:17:30
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
	(b) (4)	
User entered '10:00' reason for change: Data Entry Error	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Jan 2021 10:00'	System	04 Feb 2021 22:20:22
User entered '18 Sep 2020 10:00'	System	25 Nov 2020 15:18:03
User entered empty.	System	23 Oct 2020 13:10:38
User entered '18 Sep 2020 10:00'	System	22 Sep 2020 19:49:42
User entered empty.	System	14 Sep 2020 17:23:42

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:23:42

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:45:36
Query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'changed in edc' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:23:35
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:23:29
User opened query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:11:08
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:57:02
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	14 Dec 2020 19:17:45
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:15:36



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	21 Nov 2020 20:44:20
User entered 'None (NONE)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'I'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Brenda Anderson (b) (4)	25 Nov 2020 15:18:26
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	14 Sep 2020 17:24:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:23:42



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:23:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:57
Data point term sent to Coder	System	19 Feb 2021 21:24:51
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 04:30:18
User closed query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., GENERALIZED, BOTH KNEES, RIGHT SHOULDER, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6) (b) (4)	09 Oct 2020 09:40:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:27:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:27:11
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'Solicited AR, per investigator related to investigation IP, No illness visit visit required. ' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:52:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., GENERALIZED, BOTH KNEES, RIGHT SHOULDER, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4)	07 Oct 2020 16:51:52
Data point term sent to Coder	System	07 Oct 2020 16:51:52
Coding entries removed.	Sheldon Warren (b) (4)	07 Oct 2020 16:51:01
User entered 'shoulders and right hip MUSCLE ACHES' reason for change: Data Entry Error	Sheldon Warren (b) (4)	07 Oct 2020 16:51:01
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:45:47
User opened query 'Per DM CLR: Please specify the location of JOINT ACHES (e.g., GENERALIZED, BOTH KNEES, RIGHT SHOULDER, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:02:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:25:46
Data point term sent to Coder	System	14 Sep 2020 17:25:21
User entered 'Muscle aches'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '30 Aug 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '10:00'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 10:00'	System	14 Sep 2020 17:25:20

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '9 Sep 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '10:00'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020 10:00'	System	14 Sep 2020 17:25:20

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'None (NONE)'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:58

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 09:01:16
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'not taken for this' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:54:45
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:02:24
User entered 'I'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:25:20



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:25:20

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:58
Data point term sent to Coder	System	19 Feb 2021 21:24:51
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 04:30:25
User closed query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6) (b) (4)	09 Oct 2020 09:40:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:33:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:33:57
Data point term sent to Coder	System	07 Oct 2020 16:55:58
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'Solicited AR, per investigator related to investigation IP, No illness visit visit required. ' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:55:48

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4)	07 Oct 2020 16:55:43
Coding entries removed.	Sheldon Warren (b) (4)	07 Oct 2020 16:55:29
User entered 'elbows and right hip JOINT ACHES' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	07 Oct 2020 16:55:29
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).	(b) (4), (b) (6)	05 Oct 2020 12:45:55
' (Site from DM).		
User opened query 'Per DM CLR: Please specify the location of MUSCLE ACHES (e.g., GENERALIZED, BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:02:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:27:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 17:27:50
Data point term sent to Coder	System	14 Sep 2020 17:27:24
User entered 'joint aches'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '30 Aug 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '10:00'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 10:00'	System	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '7 Sep 2020'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '10:00'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020 10:00'	System	14 Sep 2020 17:26:24



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'None (NONE)'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 09:01:53
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'not taken for this' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:56:01
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#9) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:02:40
User entered 'I'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:26:24

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:26:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:26:00
Data point term sent to Coder	System	19 Feb 2021 21:25:02
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:38:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:38:42
Data point term sent to Coder	System	05 Nov 2020 14:38:04
User entered 'INTERMITTENT HIVES (FACE AND NECK)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '31 Aug 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 22:26:44
	(b) (4)	
User entered '8 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:37:25

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Brenda Anderson (b) (4)	03 Feb 2021 18:17:27
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	04 Feb 2021 20:35:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Feb 2021 20:35:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Feb 2021 18:17:27
User entered '7 Jan 2021' reason for change: New Information	Brenda Anderson (b) (4)	03 Feb 2021 18:17:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:37:25

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:47:12
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:26:55
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:11:21
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 20:45:50
User entered 'Dose Delayed (DOSE DELAYED)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '1'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:47:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 20:35:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:37:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:37:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:37:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:37:25
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:37:25



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:37:25

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:59
Data point term sent to Coder	System	19 Feb 2021 21:25:03
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:25:06
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'subject had an unscheduled assessment 25sep2020. data confirmed as is' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	23 Dec 2020 20:45:38
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:57:16
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 04:55:09

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 20:59:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 20:59:41
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'Updated, however condition is still mild and does not interfere with daily activities, therefore it does not meet moderate AE criteria.' (Site from DM).	Allison Crain (b) (4) (b) (4)	27 Nov 2020 18:54:08
Data point term sent to Coder	System	27 Nov 2020 18:49:18
Coding entries removed.	Allison Crain (b) (4) (b) (4)	27 Nov 2020 18:48:25
User entered 'WORSENER INTERMITTENT HEADACHES' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	27 Nov 2020 18:48:25
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 13:43:26
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:42:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:42:21
Data point term sent to Coder	System	05 Nov 2020 14:42:09
User entered 'intermittent headaches'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '23 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:41:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:48:17
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:30
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:07
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:12:45
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	04 Feb 2021 22:31:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Feb 2021 22:31:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Feb 2021 22:31:07
User entered '23 Nov 2020' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:07
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:41:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

Severity

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:49:31
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'corrected per query' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:07
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:12:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:47:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:50:03
Query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'changed edc' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:32:08
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:31:07
User opened query 'Per DM CLR - RQ: Site's response noted. However, note than on Dosing Discontinuation page, only AE #5 is recorded. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:12:23
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:57:31
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify.' answered with 'added' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	14 Dec 2020 19:20:08
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation page if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 05:19:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 20:46:57

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'I'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (9)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 22:31:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:42:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:42:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:42:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:41:52
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:41:52

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:41:52

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Folder: Adverse Events

Form: Adverse Events (10)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User closed query 'Per MM: please confirm if the subject was diagnosed with COVID-19. If not, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 02:54:11
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 16:32:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 16:32:48
Data point term sent to Coder	System	18 Mar 2021 16:31:52
Query 'Per MM: please confirm if the subject was diagnosed with COVID-19. If not, please update the actual diagnosis or add the individual symptoms as separate entries. ' answered with 'UPDATED' (Site from DM).	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:31:45
Coding entries removed.	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:31:40
Signature has been broken.	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:31:40
User entered 'COVID LIKE ILLNESS' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:31:40
User opened query 'Per MM: please confirm if the subject was diagnosed with COVID-19. If not, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:22:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:26:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:26:00
Data point term sent to Coder	System	19 Feb 2021 21:25:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if the subject was tested for Covid-19 infection. If yes, please update the AE term accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:48:56
Query 'Per CDM: Please confirm if the subject was tested for Covid-19 infection. If yes, please update the AE term accordingly.' answered with 'Subject tested for Covid-19, did not test positive.' (Site from DM).	Allison Crain (b) (4) (b) (4)	14 Feb 2021 17:00:54
User opened query 'Per CDM: Please confirm if the subject was tested for Covid-19 infection. If yes, please update the AE term accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:31:13
Query 'Per CDM: Please confirm if the subject tested positive for Covid-19 infection. If yes, please update the AE term accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:27:50
User opened query 'Per CDM: Please confirm if the subject tested positive for Covid-19 infection. If yes, please update the AE term accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:27:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 14:04:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 14:04:37
Data point term sent to Coder	System	04 Feb 2021 22:55:45
User entered 'covid like symptom'	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:54:55

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	



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**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '14 Oct 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
	(b) (4)	
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 22:54:55

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:08:39
User entered '07 Jan 2021' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
	(b) (4)	
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 22:54:55
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 22:54:55

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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 Feb 2021 23:08:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	04 Feb 2021 23:08:39
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
User entered empty.	(b) (4)	
	System	04 Feb 2021 22:54:55
	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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 Feb 2021 23:08:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	04 Feb 2021 23:08:39
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
User entered empty.	(b) (4)	
	System	04 Feb 2021 22:54:55
	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'None (NONE)'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	04 Feb 2021 23:08:39
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Feb 2021 22:54:55
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:54:55

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:47:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
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 Feb 2021 23:08:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	System	04 Feb 2021 23:08:39
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 23:08:39
User entered empty.	(b) (4)	
	System	04 Feb 2021 22:54:55
	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	04 Feb 2021 22:54:55
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 22:54:55

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 22:54:55



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 02:54:38
Query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' answered with 'Not Covid-19. Unknown organism per labs.' (Site from DM).	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:29:07
User opened query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:22:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:25:57
Data point term sent to Coder	System	19 Feb 2021 21:25:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 15:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 15:57:48
Data point term sent to Coder	System	10 Feb 2021 15:57:11
User entered 'viral upper respiratory infection'	Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 15:56:35

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '25 Jan 2021'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 15:56:35

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '28 Jan 2021'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 15:56:35

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	



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Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 15:56:35

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'None (NONE)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 02:55:55
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Please see ConMed logline #17' (Site from DM).	Allison Crain (b) (4) (b) (4)	18 Mar 2021 16:31:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:52:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:24:44
User entered 'I'	Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 15:56:35

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:24:44
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 15:56:35
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 15:56:35

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 15:56:35

US3512176

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Mar 2021 15:56:01
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 15:56:01
Data point term sent to Coder	System	03 Mar 2021 16:14:24
User entered 'worsening acid reflux'	Brenda Anderson (b) (4) (b) (4)	03 Mar 2021 16:13:33

US3512176

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 15:53:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 15:53:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Mar 2021 15:53:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:13:33
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 15:01:11
User entered '25 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	23 Mar 2021 15:01:11
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:54:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 15:54:14
User entered 'UN Nov 2020' (non-conformant).	Allison Crain (b) (4)	04 Mar 2021 15:54:14
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Mar 2021 16:13:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Mar 2021 16:13:47
User entered 'Nov 2020' (non-conformant).	Brenda Anderson (b) (4)	03 Mar 2021 16:13:47
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Mar 2021 16:13:33
User entered 'un Nov 2020' (non-conformant).	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 16:13:33

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 09:37:58
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'per source still ongoing' (Site from DM).	Brenda Anderson (b) (4)	31 Mar 2021 21:56:35
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or has returned to baseline state and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4)	
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'Yes (Y)'	(b) (4)	
	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 16:13:33

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'None (NONE)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'I'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 16:13:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 16:13:33

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 15:53:25

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 11:21:35
Data point term sent to Coder	(b) (4)	
User entered 'worsening Osteoarthritis right hip'	Coder Import (b) (4)	01 Apr 2021 11:21:35
	(b) (4)	
	System	31 Mar 2021 21:57:50
	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '22 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:57:48

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:57:48

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	



US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:47:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'None (NONE)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'I'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	



**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Anderson (b) (4)	31 Mar 2021 21:57:48
	(b) (4)	

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	14 Apr 2021 16:44:20
User entered empty.	Brenda Anderson (b) (4) (b) (4)	31 Mar 2021 21:57:48

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	14 Apr 2021 16:44:20
User entered empty.	Brenda Anderson (b) (4) (b) (4)	31 Mar 2021 21:57:48

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 21:57:48

**US3512176**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 11 Aug 2021 22:47:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 21:57:48

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:47:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:11
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:13:32

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Aug 2020 17:30:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 17:30:39
Data point term sent to Coder	System	29 Aug 2020 17:14:42
User entered 'HYDROCHLOROTHIAZIDE'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:14:24



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'HYPERTENSION'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '25'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:14:24

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	



US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 1980'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:14:24
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:14:24

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:14:24



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 17:14:24

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Aug 2020 17:16:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 17:16:41
Data point term sent to Coder	System	29 Aug 2020 17:15:43
User entered 'LEVOTHYROXINE'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:15:04

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'HYPOTHYROIDISM'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:15:04

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '112'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'ug (ug)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:15:04

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 1978'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:15:04
	(b) (4)	



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:15:04

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:15:04

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 17:15:04

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Aug 2020 05:17:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:17:44
Data point term sent to Coder	System	29 Aug 2020 17:16:44
User entered 'ZOLOFT'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:15:55

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'ANXIETY/FIBROMYALGIA'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:15:55

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '50'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	



US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:15:55

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 1981'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:15:55
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:15:55

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:15:55

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 17:15:55

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS FUMARATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 00:21:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:21:45
Data point term sent to Coder	System	29 Aug 2020 17:16:44
User entered 'FERROUS FUMARATE'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:30

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'SUPPLEMENT'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:30



US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '18'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:30

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:30

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 2003'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:16:30
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:16:30

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:16:30

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 17:16:30

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Aug 2020 06:22:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Aug 2020 06:22:55
Data point term sent to Coder	System	29 Aug 2020 17:17:45
User entered 'PRILOSEC OTC'	Allison Crain (b) (4)	29 Aug 2020 17:16:58



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'ACID REFLUX'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '20'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'mg (mg)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'as needed (PRN)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:58



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'UN UNK 2018'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
Signature has been broken.	Brenda Anderson (b) (4)	03 Mar 2021 17:25:36
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	03 Mar 2021 17:25:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
Signature has been broken.	Brenda Anderson (b) (4)	03 Mar 2021 17:25:36
User entered '2 Mar 2021' reason for change: Data Entry Error	Brenda Anderson (b) (4)	03 Mar 2021 17:25:36
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User entered empty.	System	29 Aug 2020 17:16:58

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User entered empty.	System	29 Aug 2020 17:16:58



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:43
User entered empty.	System	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:01:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 17:01:24
Data point term sent to Coder	System	07 Oct 2020 17:00:05
Coding entries removed.	Sheldon Warren (b) (4)	07 Oct 2020 16:59:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 17:18:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 17:18:42
Data point term sent to Coder	System	29 Aug 2020 17:17:46
User entered 'VITAMIN D'	Allison Crain (b) (4)	29 Aug 2020 17:17:40

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per DM CLR: Please confirm if this Con Med was given for MH #10. If yes, please update Con Med indication to reflect a match with MH #10 as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 04:57:54
Query 'Per DM CLR: Please confirm if this Con Med was given for MH #10. If yes, please update Con Med indication to reflect a match with MH #10 as appropriate. ' answered with 'update' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:00:08
User entered 'vitamin D deficiency' reason for change: Data Entry Error	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:59:54
User opened query 'Per DM CLR: Please confirm if this Con Med was given for MH #10. If yes, please update Con Med indication to reflect a match with MH #10 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:28:57
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:17:40

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '2000'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'IU (IU)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:17:40

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:17:40

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 2015'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:17:40
	(b) (4)	



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:17:40

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 17:17:40

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 17:17:40

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Aug 2020 17:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 17:19:43
Data point term sent to Coder	System	29 Aug 2020 17:18:47
User entered 'IBUPROFEN'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:06

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'HEADACHES'	(b) (4) Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:06

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '200'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	



US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:06

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'as needed (PRN)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 1990'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:18:06
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 17:18:06

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 17:18:06

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 17:18:06

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:24:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:24:35
	(b) (4)	
Data point term sent to Coder	System	29 Aug 2020 17:19:50
User entered 'FISH OIL'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'HIGH TRIGLYCERIDES'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '1200'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 04:59:06
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4)	07 Oct 2020 17:01:10
User entered 'mg (mg)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	07 Oct 2020 17:00:58
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:29:23
User entered 'Other (OTHER)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	07 Oct 2020 17:00:58
	(b) (4)	
User entered 'UNITS'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	15 Jan 2021 17:46:51
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'un Jun 2020' reason for change: New Information	Sheldon Warren (b) (4)	15 Jan 2021 17:46:51
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	29 Aug 2020 17:18:57
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User entered '1'	System	29 Aug 2020 17:18:57

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User entered '1'	System	29 Aug 2020 17:18:57

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:04:09
User entered '804 (804)'	System	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:28:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 18:28:49
Data point term sent to Coder	System	08 Sep 2020 18:27:45
User entered 'Advil'	Sheldon Warren (b) (4)	08 Sep 2020 18:27:13



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Headache'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '200'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'other (OTHER)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'EVERY 2 hours' reason for change:	(b) (4)	
New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:52:23
User entered 'every 4-6 hours'	(b) (4)	
	Sheldon Warren (b) (4)	08 Sep 2020 18:27:13
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding AE. Please reconcile and update applicable details accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:10:59
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding AE. Please reconcile and update applicable details accordingly. Otherwise, clarify. ' answered with 'updated ' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:28:22
User entered '31 Aug 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:28:15
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding AE. Please reconcile and update applicable details accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:11:00
User entered '30 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)' reason for change: New Information	(b) (4) Sheldon Warren (b) (4)	22 Sep 2020 19:52:23
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '20 Sep 2020' reason for change: New Information	(b) (4)	
	Sheldon Warren (b) (4)	22 Sep 2020 19:52:23
User entered empty.	(b) (4)	
	Sheldon Warren (b) (4)	08 Sep 2020 18:27:13
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Sep 2020 18:27:13

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User entered empty.	System	08 Sep 2020 18:27:13

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User entered empty.	System	08 Sep 2020 18:27:13



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:49
User entered empty.	System	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
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)	15 Oct 2020 18:57:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 18:57:30
Data point term sent to Coder	System	15 Oct 2020 18:56:36
User entered 'influenza vaccine'	Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'seasonal influenza'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'I'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Other (OTHER)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'injection'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'once (ONCE)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '8 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '8 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Oct 2020 18:55:41



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User entered empty.	System	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User entered empty.	System	15 Oct 2020 18:55:41

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:18:54
User entered empty.	System	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;ZINC ACETATE, PRODUCTSYNONYM: EQUATE ANTI ITCH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:37:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:37:20
Data point term sent to Coder	System	05 Nov 2020 14:29:53
User entered 'equate anti itch diphenhydramine'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'intermittent hives'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'I'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Other (OTHER)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'application'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'as needed (PRN)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Topical (TOPICAL)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '10 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:01:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:01:34
Signature has been broken.	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:01:23
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	16 Mar 2021 12:01:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:28:43
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:29:03



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
Signature has been broken.	Allison Crain (b) (4)	16 Mar 2021 12:01:23
User entered '7 Jan 2021' reason for change: Data Entry Error	Allison Crain (b) (4)	16 Mar 2021 12:01:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User entered empty.	System	05 Nov 2020 14:29:03

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User entered empty.	System	05 Nov 2020 14:29:03

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:00
User entered empty.	System	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:39:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:39:37
Data point term sent to Coder	System	23 Mar 2021 14:38:30
Coding entries removed.	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:38:17
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:40:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:40:28
Data point term sent to Coder	System	04 Feb 2021 22:39:35
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:39:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:31:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:31:26
Data point term sent to Coder	System	05 Nov 2020 14:30:53
User entered 'tylenol'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of LOWER BACK ACHE during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 06:23:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of LOWER BACK ACHE during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:38:24
Signature has been broken.	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:38:17
User entered 'COVID-LIKE ILLNESS' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	23 Mar 2021 14:38:17
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of LOWER BACK ACHE during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:00:51
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered 'LOWER BACK/HEADACHE' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:39:16
User entered 'lower back headache'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:30:27



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
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	19 Nov 2020 13:30:18
User entered '325' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:30:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Nov 2020 14:30:27
	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
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	19 Nov 2020 13:30:18
User entered 'mg (mg)' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:30:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Nov 2020 14:30:27
	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'as needed (PRN)'	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '14 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Brenda Anderson (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 02:04:26
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	06 Apr 2021 15:01:37
Signature has been broken.	Allison Crain (b) (4) (b) (4)	06 Apr 2021 15:01:32
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	06 Apr 2021 15:01:32
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:17:59
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:08
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	06 Apr 2021 15:01:32
	(b) (4)	
User entered '7 Jan 2021' reason for change: Data Entry Error	Allison Crain (b) (4)	06 Apr 2021 15:01:32
	(b) (4)	
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:30:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:58

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, CM was given after AE reporting period and is not recorded in Diary. Review if this should be updated to NO. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:39:23
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, CM was given after AE reporting period and is not recorded in Diary. Review if this should be updated to NO. Else, clarify.' answered with 'corrected per query' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:41:57
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 22:41:47
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, CM was given after AE reporting period and is not recorded in Diary. Review if this should be updated to NO. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:08:57
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:30:27

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User entered empty.	System	05 Nov 2020 14:30:27

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User entered empty.	System	05 Nov 2020 14:30:27

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:05
User entered empty.	System	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 23:11:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 23:11:31
Data point term sent to Coder	System	04 Feb 2021 23:10:57
Coding entries removed.	Brenda Anderson (b) (4)	04 Feb 2021 23:10:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 17:48:54
Data point term sent to Coder	System	15 Jan 2021 17:46:40
User entered 'prednisone'	Sheldon Warren (b) (4)	15 Jan 2021 17:45:53



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per DM CLR: Please remove the word 'PREVENTION' as there is an ongoing AE recorded (AE7) that matches this medication. Please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:39:48
Query 'Per DM CLR: Please remove the word 'PREVENTION' as there is an ongoing AE recorded (AE7) that matches this medication. Please update indication as appropriate. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 23:11:01
User entered 'HIVES' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 23:10:56
User opened query 'Per DM CLR: Please remove the word 'PREVENTION' as there is an ongoing AE recorded (AE7) that matches this medication. Please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:57:16
User entered 'hives prevention'	Sheldon Warren (b) (4) (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '20'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered empty.	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '6 Jan 2021'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '0'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	03 Feb 2021 18:10:09
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '7 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	03 Feb 2021 18:10:09
User entered empty.	(b) (4)	
	Sheldon Warren (b) (4)	15 Jan 2021 17:45:53
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	15 Jan 2021 17:45:53

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User entered empty.	System	15 Jan 2021 17:45:53

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User entered empty.	System	15 Jan 2021 17:45:53



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:14
User entered empty.	System	15 Jan 2021 17:45:53

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 06:19:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 06:19:48
Data point term sent to Coder	System	03 Mar 2021 17:26:37
User entered 'prilosec OTC'	Brenda Anderson (b) (4) (b) (4)	03 Mar 2021 17:26:36

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'worsening acid reflux'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '40'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Mar 2021 14:25:24
User entered empty.	Brenda Anderson (b) (4) (b) (4)	03 Mar 2021 17:26:36

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'once daily (QD)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '3 Mar 2021'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	03 Mar 2021 17:26:36
	(b) (4)	



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 17:26:36

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 17:26:36

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 17:26:36

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:06:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:06:42
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4) (b) (4)	09 Apr 2021 13:06:14 09 Apr 2021 13:05:28
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Mar 2021 14:25:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 20:31:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 20:31:00
Data point term sent to Coder User entered 'tylenol'	System Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 20:30:20 12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:20
Signature has been broken.	Allison Crain (b) (4)	09 Apr 2021 13:05:28
User entered 'HEADACHES' reason for change: Data Entry Error	Allison Crain (b) (4)	09 Apr 2021 13:05:28
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'headache'	Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '750'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '5 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '0'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '6 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 20:29:20

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User entered empty.	System	12 Mar 2021 20:29:20

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User entered empty.	System	12 Mar 2021 20:29:20

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:24
User entered empty.	System	12 Mar 2021 20:29:20

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 16:31:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 16:31:39
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	18 Mar 2021 16:30:51 18 Mar 2021 16:30:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 12:00:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 12:00:49
Data point term sent to Coder User entered 'TYLENOL'	System Allison Crain (b) (4)	16 Mar 2021 11:59:33 16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'VIRAL UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	18 Mar 2021 16:30:28
User entered 'COVID-LIKE ILLNESS'	(b) (4)	
	Allison Crain (b) (4)	16 Mar 2021 11:58:39
	(b) (4)	



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '325'	Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'mg (mg)'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'once (ONCE)'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
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	16 Mar 2021 11:59:07
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Allison Crain (b) (4)	16 Mar 2021 11:59:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Mar 2021 11:58:39
	Allison Crain (b) (4)	16 Mar 2021 11:58:39
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '26 Jan 2021'	Allison Crain (b) (4)	16 Mar 2021 11:58:39



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '0'	Allison Crain (b) (4)	16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered '26 Jan 2021'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:47:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:24
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User entered empty.	System	16 Mar 2021 11:58:39

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User entered empty.	System	16 Mar 2021 11:58:39

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:29
User entered empty.	System	16 Mar 2021 11:58:39

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:15:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:15:10
Data point term sent to Coder	System	05 Apr 2021 10:53:17
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:53:14
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:06:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	02 Apr 2021 19:29:03
Data point term sent to Coder	System	31 Mar 2021 21:59:52
User entered 'advil'	Brenda Anderson (b) (4) (b) (4)	31 Mar 2021 21:59:27



US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'worsening osteoarthritis right hip'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '400'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'as needed (PRN)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	



US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '22 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:47:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:03
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 21:59:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:59:27

**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:59:27



**US3512176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Aug 2021 22:47:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:59:27

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:47:58**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 15:58:04
	(b) (4)	

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**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:47:58**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:08:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered '30 Sep 2020'	Allison Crain (b) (4)	19 Nov 2020 13:53:45

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:58

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:08:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User closed query 'Per CDM: Day 29 Exposure Form shows IP not given due to Adverse Event and Reason for Dosing Discontinuation is also recorded as Adverse Event(s); however, there are Adverse Events presently recorded with Action with IP as IP Withdrawn. Please reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 23:28:42
Query 'Per CDM: Day 29 Exposure Form shows IP not given due to Adverse Event and Reason for Dosing Discontinuation is also recorded as Adverse Event(s); however, there are Adverse Events presently recorded with Action with IP as IP Withdrawn. Please reconcile and update accordingly.' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 20:43:03
User opened query 'Per CDM: Day 29 Exposure Form shows IP not given due to Adverse Event and Reason for Dosing Discontinuation is also recorded as Adverse Event(s); however, there are Adverse Events presently recorded with Action with IP as IP Withdrawn. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:46:26
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:57:32
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:53:45

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:58

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)	28 Apr 2021 04:08:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:26:58
User entered 'AE # 7' reason for change: Per Query Resolution	Brenda Anderson (b) (4)	04 Feb 2021 22:27:18
User closed query 'Per DM CLR RQ: As per CCGs, only one AE can be recorded for Study drug withdrawn so please review and update correct reason for dosing discontinuation.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:07:33
Query 'Per DM CLR RQ: As per CCGs, only one AE can be recorded for Study drug withdrawn so please review and update correct reason for dosing discontinuation.' answered with 'will change EDC per query in EDC source will document what patient reported. Sub- investigator rvw'd and chose appropriate AE' (Site from DM).	Brenda Anderson (b) (4)	16 Dec 2020 15:30:58
User entered 'AE # 5' reason for change: Per Query Resolution	Brenda Anderson (b) (4)	16 Dec 2020 15:28:22
User opened query 'Per DM CLR RQ: As per CCGs, only one AE can be recorded for Study drug withdrawn so please review and update correct reason for dosing discontinuation.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:56:35
User entered 'AE # 1, 2, 5, 7, 8, 9' reason for change: New Information	Brenda Anderson (b) (4)	14 Dec 2020 19:19:38
User entered 'AE # 1,2,4,5,6,7' reason for change: New Information	Brenda Anderson (b) (4)	14 Dec 2020 19:16:58
User closed query 'Per CDM: Thank You for the response, however, AE # 6 has been inactivated. Kindly reconcile and update AE log line accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:36:27
Query 'Per CDM: Thank You for the response, however, AE # 6 has been inactivated. Kindly reconcile and update AE log line accordingly.' answered with 'updated' (Site from DM).	Allison Crain (b) (4)	02 Dec 2020 21:28:37
User entered 'AE #5 AND AE #7' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Dec 2020 21:28:33
User opened query 'Per CDM: Thank You for the response, however, AE # 6 has been inactivated. Kindly reconcile and update AE log line accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:24:25

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EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:58

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs). Please add only one AE which the PI considers "Primary"' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:21:38
Query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs). Please add only one AE which the PI considers "Primary"' answered with 'The site cannot find anywhere in the guidelines stating there needs to be one primary cause of dose discontinuation. All of the causes stated are accurate. Please contact the monitor with any further questions as both causes together are the primary cause.' (Site from DM).	Allison Crain (b) (4) (b) (4)	27 Nov 2020 18:40:54
User opened query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs). Please add only one AE which the PI considers "Primary"' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:07:21
User closed query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs).' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:48:24
Query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs).' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	25 Nov 2020 15:36:51
User entered 'AE #5 and AE #6' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	25 Nov 2020 15:36:43
User opened query 'Per CDM: it appears to several events lading to dosing discontinuation. Please determine primary cause and update this data field with AE record number without details (per CCGs).' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:28:14

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EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:58

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: please record AE record number instead of details.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:43:53
User opened query 'Per CDM: please record AE record number instead of details.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:12:03
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:57:32
User entered 'Due to the subject's AE's of fatigue, headache, and intermittent hives that began after the first injection, subject wished not to get the second dose of IP. She still wishes to participate in study.' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:57:32
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 13:53:45
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:53:45