

US3512176 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:29:22

All time stamps listed in this document are displayed in GMT

US3512176

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:22

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:29:22

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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:22

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

Condition	SHELLFISH ALLERGY
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	UNKNOWN POOL CHEMICALS ALLERGY
Start date (dd MMM yyyy)	15 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	IRRITABLE BOWL SYNDROME
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	COLON POLYPS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (13)

Generated On: 26 Nov 2020 09:29:22

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1964
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	STROKE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (16)

Generated On: 26 Nov 2020 09:29:22

Condition	VERTIGO
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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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Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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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Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	BROKEN LEFT ELBOW
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	HIGH TRIGLYCERIDES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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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Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	SWELLING IN LOWER EXTREMITIES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:29:22

Condition	POST-PARTUM DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	TONSILITIS
Start date (dd MMM yyyy)	UN UNK 1952
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1952
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	BREAST REDUCTION
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	SHATTERED LEFT ELBOW
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	SHATTERED LEFT ELBOW REPAIR
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

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 ☐ No ☒
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)

Generated On: 26 Nov 2020 09:29:22

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

Condition	COLON RESECTION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (40)

Generated On: 26 Nov 2020 09:29:22

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (41)

Generated On: 26 Nov 2020 09:29:22

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (42)

Generated On: 26 Nov 2020 09:29:22

Condition	LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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 (43)

Generated On: 26 Nov 2020 09:29:22

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Were vital signs assessed?	Yes ☒
	No ☐
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 ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

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.

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 1998
Date of last menstruation unknown	False

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

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
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	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

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Height	ND - Not Done
Weight	ND - Not Done

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 09:29:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Collection date (<i>dd MMM yyyy</i>)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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 TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	96.3 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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 ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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 ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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 ☒

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Yes ☐	
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 11

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

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 15

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

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 17

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

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 18

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

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None ☐

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 10

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 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 11

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

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 11

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

No ☒

Yes ☐

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 12

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

No ☒

Yes ☐

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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 16

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

No ☒

Yes ☐

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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 21

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

No ☒

Yes ☐

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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 09:29:22

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

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

US3512176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 103

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 145

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

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

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05 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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12 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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15 FEB 2021 00:01

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19 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 FEB 2021 00:01

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26 FEB 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

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

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05 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

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

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12 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

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

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26 MAR 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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09 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 JUL 2021 00:01

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23 JUL 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

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06 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 AUG 2021 00:01

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13 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 AUG 2021 00:01

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20 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 AUG 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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10 SEP 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

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17 SEP 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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°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: 26 Nov 2020 09:29:22

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

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04 FEB 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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11 FEB 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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°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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

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08 APR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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01 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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12 AUG 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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26 AUG 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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12 SEP 2022 00:01

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16 SEP 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:29:22

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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26 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: 26 Nov 2020 09:29:22

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

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10 OCT 2022 00:01

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14 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:29:22

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:22

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	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	393 of 2747	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

	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)

Generated On: 26 Nov 2020 09:29:22

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	397 of 2747	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

	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)

Generated On: 26 Nov 2020 09:29:22

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	401 of 2747	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

	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)

Generated On: 26 Nov 2020 09:29:22

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	405 of 2747	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

	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: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

Date of Visit	23 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	23 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:22

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:29:22

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 Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:56 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:56
Height (<i>xxx.x</i>)	60.25 in
Weight (<i>xxx.x</i>)	96.1 kg
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	SICKD28

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:29:22

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

Generated On: 26 Nov 2020 09:29:22

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)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	HEADACHE
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	FATIGUE
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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:29:22

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 ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	ELBOWS AND RIGHT HIP JOINT 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)	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 ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (5)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	INTERMITTENT HIVES ON FACE AND NECK
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (6)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	INTERMITTENT HIVES (FACE AND NECK)
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)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☒ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	INTERMITTENT HIVES (FACE AND NECK)
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)	8 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (8)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	INTERMITTENT FATIGUE
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)	19 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (9)

Generated On: 26 Nov 2020 09:29:22

AEID	
Adverse event	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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:29:22

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1980
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1978
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1981
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:22

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:22

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	
Route of administration	EVERY 2 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		20 SEP 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intramuscular ☒

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

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 ☐ Intraocular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:22

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	LOWER BACK HEADACHE
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 ☐ Intramuscular ☐

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3512176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:22

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3512176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:22

Date of dosing discontinuation (dd MMM yyyy)

30 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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.

US3512176

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3512176'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 11:45:43

US3512176

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:03

US3512176

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 11:45:44

US3512176

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:03

US3512176

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Aug 2020 13:29:03

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 11:45:45

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Age](#)

Audit	User	Time (GMT)
User entered '71'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '71'	System	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[White](#)

Audit	User	Time (GMT)
User entered '1'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:22

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:22

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:38

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 11:45:44

US3512176

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:22

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:29:43

US3512176

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:20

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1965'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1965'	System	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1965'	System	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:15:48

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:16:27

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:16:49

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:17:21

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2019' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:52
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2019' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:52
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:17:35

US3512176

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	29 Aug 2020 15:19:41
Data point term sent to Coder	System	29 Aug 2020 15:19:07
User entered 'irritable bowl syndrome'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:18:24

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2016'	System	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:18:43

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:19:13

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1980'	System	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:19:38

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:19:56

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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.	(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
	(b) (4)	

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:20:14

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1960'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1960'	System	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:20:41

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1964'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1964'	System	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1964'	System	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:21:04

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1960'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1960'	System	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:22:50

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 15:23:08

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:23:19

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1980'	System	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:24:36

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:24:51

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 15:25:09

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2010'	System	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:25:29

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1978'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1978'	System	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1978'	System	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:25:52

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1960'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1960'	System	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:26:06

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLG: 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: Data Entry Error	Allison Crain (b) (4)	29 Aug 2020 16:54:45
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1980'	System	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:26:38

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:27:06

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	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
	(b) (4)	

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1981'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1981'	System	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 15:27:39

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Perinatal depression, 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1979'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 1980'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Taylor Johnson (b) (4) (b) (4)	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1979'	System	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1979'	System	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1980'	System	29 Aug 2020 15:28:16

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1952'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1952'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1952'	System	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1952'	System	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1952'	System	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1952'	System	29 Aug 2020 16:55:21

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1952'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1952'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1952'	System	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1952'	System	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1952'	System	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1952'	System	29 Aug 2020 16:56:01

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1959'	System	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1959'	System	29 Aug 2020 16:56:17

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1959'	System	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1959'	System	29 Aug 2020 16:56:37

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1982'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1982'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1982'	System	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1982'	System	29 Aug 2020 16:56:56

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1985'	System	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (32)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1985'	System	29 Aug 2020 16:57:27

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2002'	System	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (33)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 16:58:10

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (34)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 16:58:32

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (35)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	29 Aug 2020 16:59:11

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2004'	System	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (36)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2004'	System	29 Aug 2020 16:59:53

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2005'	System	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (37)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2005'	System	29 Aug 2020 17:00:13

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2012'	System	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (38)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2012'	System	29 Aug 2020 17:00:32

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (39)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 17:02:33

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
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) (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)	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 17:03:29
User entered 'HYSTERECTOMY'	Allison Crain (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (40)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 17:02:50

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (41)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 17:03:15

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (42)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 17:03:34

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 13:45:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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
	(b) (4)	

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1998'	System	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Medical History (43)

Generated On: 26 Nov 2020 09:29:22

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 13:44:30

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '07:26'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 07:26'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '60.25' in	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: 26 Nov 2020 09:29:22

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '212.4' lb	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: 26 Nov 2020 09:29:22

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:05:14

US3512176

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:35

US3512176

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:35

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

If No, what is the reason?

Audit	User	Time (GMT)
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) (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)	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)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:42:54
User entered 'UN UNK 1988'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:29:22

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:07:26

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:22

[Specify](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER (RESTAURANTS, COMMUNITY POOL); INTERACTS W/>5 PEOPLE A DAY OUTSIDE WORK OR HOME'	Allison Crain (b) (4)	29 Aug 2020 17:09:11

US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:01

US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:01

US3512176

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Aug 2020 13:30:01

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '188367'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 11:55:32

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:09:30

US3512176

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:22

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (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)	04 Nov 2020 17:38:37
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:51:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:35:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:35:18

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 09:29:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	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: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '07:26'	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: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	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: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	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: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '137'	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: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	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: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:22

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:10:14

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	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: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:38'	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: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	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: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	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: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '153'	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: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '95'	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: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 17:10:51

US3512176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:09

US3512176

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:09

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:07'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 09:07'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 13:37:44

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:11:07

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:11:07

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:59'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:11:07

US3512176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	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: 26 Nov 2020 09:29:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '07:44'	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: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 17:11:25

US3512176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 13:30:25

US3512176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 13:30:25

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:39:27
User entered 'Yes (Y)'	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:39:27
User entered '97.6'	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:39:27
User entered 'No (N)'	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:39:27
User entered '29 Aug 2020 09:39'	System	29 Aug 2020 13:39:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	30 Aug 2020 00:04:10
User entered 'Yes (Y)'	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	30 Aug 2020 00:04:10
User entered '97.8'	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 00:04:10
User entered 'No (N)'	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 00:04:10
User entered '29 Aug 2020 20:04'	System	30 Aug 2020 00:04:10

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	30 Aug 2020 22:30:27
User entered '96.5'	System	30 Aug 2020 22:30:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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). 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 '1'	Sheldon Warren (b) (4)	08 Sep 2020 18:37:39
	System	30 Aug 2020 22:30:27
	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: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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 '0'	System	30 Aug 2020 22:30:27

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:28:50
User entered '97.8'	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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).	Sheldon Warren (b) (4)	08 Sep 2020 18:38:17
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 '1'	System	01 Sep 2020 02:28:50

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:57:44
User entered 'Yes (Y)'	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:57:44
User entered '96.2'	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:57:44
User entered 'No (N)'	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:57:44
User entered '01 Sep 2020 20:57'	System	02 Sep 2020 00:57:44

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:15:58
User entered 'Yes (Y)'	System	03 Sep 2020 02:15:58

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:15:58
User entered '97.5'	System	03 Sep 2020 02:15:58

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:10:43
User entered 'Yes (Y)'	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:10:43
User entered '97.3'	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:10:43
User entered 'No (N)'	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:10:43
User entered '03 Sep 2020 21:10'	System	04 Sep 2020 01:10:43

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:19
User entered 'Yes (Y)'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:19
User entered '96.5'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:19
User entered 'Yes (Y)'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Nov 2020 07:36:03
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).	Allison Crain (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'	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: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:19
User entered '0'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:19
User entered '04 Sep 2020 19:02'	System	04 Sep 2020 23:02:19

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:03:53
User entered '97.5'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Nov 2020 07:36:11
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).	Allison Crain (b) (4)	19 Nov 2020 13:49:15
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	06 Sep 2020 11:03:53
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'	System	06 Sep 2020 11:03:53
User entered '1'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:03:53
User entered '0'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:03:53
User entered '06 Sep 2020 07:03'	System	06 Sep 2020 11:03:53

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:11:17
User entered '96.9'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Nov 2020 07:36:24
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).	Allison Crain (b) (4)	19 Nov 2020 13:49:22
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	07 Sep 2020 02:11:17
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: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Nov 2020 07:36:26
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).	Allison Crain (b) (4)	19 Nov 2020 13:49:27
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).	System	07 Sep 2020 02:11:17
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:11:17
User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:11:17

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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). 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'	Allison Crain (b) (4)	19 Nov 2020 13:49:35
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: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:46:49
User entered '96.3'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	20 Nov 2020 07:36:46
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).	Allison Crain (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'	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: 26 Nov 2020 09:29:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:46:49
User entered '0'	System	09 Sep 2020 01:46:49

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:09
User entered 'Yes (Y)'	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 26 Nov 2020 09:29:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:09
User entered '96.4'	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:09
User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:09

US3512176

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:15
User entered 'No (N)'	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:15
User entered 'No (N)'	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:15
User entered '29 Aug 2020 09:40'	System	29 Aug 2020 13:40:15

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:02:26
User entered 'No (N)'	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:02:26
User entered 'No (N)'	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:02:26
User entered '29 Aug 2020 23:02'	System	30 Aug 2020 03:02:26

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:58:07
User entered 'No (N)'	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:58:07
User entered 'No (N)'	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Sep 2020 00:58:07
User entered '01 Sep 2020 20:58'	System	02 Sep 2020 00:58:07

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:12:00
User entered 'None (1)'	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:12:00
User entered 'No (N)'	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:12:00
User entered 'None (1)'	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:12:00
User entered '03 Sep 2020 21:11'	System	04 Sep 2020 01:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:39
User entered 'No (N)'	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:39
User entered 'No (N)'	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:22

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:02:39
User entered '04 Sep 2020 19:02'	System	04 Sep 2020 23:02:39

US3512176

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered 'None (0)'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered 'None (0)'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered 'None (0)'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered 'None (0)'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered 'No (N)'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Aug 2020 13:40:53
User entered '29 Aug 2020 09:40'	System	29 Aug 2020 13:40:53

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered 'None (0)'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered 'None (0)'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered 'None (0)'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered 'None (0)'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered 'No (N)'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 03:03:16
User entered '29 Aug 2020 23:03'	System	30 Aug 2020 03:03:16

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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'	System	30 Aug 2020 22:33:15
User entered 'None (0)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	30 Aug 2020 22:33:15
User entered 'None (0)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	30 Aug 2020 22:33:15
User entered 'None (0)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 22:33:15
User entered 'No (N)'	System	30 Aug 2020 22:33:15

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered 'None (0)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered 'None (0)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered 'None (0)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered 'None (0)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered 'No (N)'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	01 Sep 2020 02:30:13
User entered '31 Aug 2020 22:30'	System	01 Sep 2020 02:30:13

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	02 Sep 2020 01:03:17
User entered 'None (0)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	02 Sep 2020 01:03:17
User entered 'None (0)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	02 Sep 2020 01:03:17
User entered 'No (N)'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Sep 2020 01:03:17
User entered '01 Sep 2020 21:03'	System	02 Sep 2020 01:03:17

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:17:40
User entered 'None (0)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:17:40
User entered 'None (0)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:17:40
User entered 'None (0)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:17:40
User entered 'No (N)'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	03 Sep 2020 02:17:40
User entered '02 Sep 2020 22:17'	System	03 Sep 2020 02:17:40

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'Some interference with activity (2)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'None (0)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'None (0)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered 'No (N)'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 01:13:18
User entered '03 Sep 2020 21:13'	System	04 Sep 2020 01:13:18

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

HEADACHE

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

FATIGUE

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'None (0)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

CHILLS

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'None (0)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered 'No (N)'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Sep 2020 23:03:37
User entered '04 Sep 2020 19:03'	System	04 Sep 2020 23:03:37

US3512176

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:02:55
User entered '06 Sep 2020 07:02'	System	06 Sep 2020 11:02:55

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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 prevents daily activity (3)'	System	07 Sep 2020 02:11:43

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:11:43
User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:11:43

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:37:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 02:37:29

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:47:09
User entered '08 Sep 2020 21:47'	System	09 Sep 2020 01:47:09

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:17
User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:17

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 02:20:22
User entered '10 Sep 2020 22:20'	System	11 Sep 2020 02:20:22

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 03:15:49
User entered '12 Sep 2020 23:15'	System	13 Sep 2020 03:15:49

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 01:33:18
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 01:33:18
User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:18

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 06:55:34
User entered '16 Sep 2020 02:55'	System	16 Sep 2020 06:55:34

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 09:59:30
User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:30

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:52:34
User entered 'None (0)'	System	18 Sep 2020 01:52:34

US3512176

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:04:15
User entered 'Significant; prevents daily activity (3)'	System	06 Sep 2020 11:04:15

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:00
User entered 'Significant; prevents daily activity (3)'	System	07 Sep 2020 02:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:00
User entered '06 Sep 2020 22:11'	System	07 Sep 2020 02:12:00

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:37:39
User entered 'Some interference with activity (2)'	System	08 Sep 2020 02:37:39

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:47:26
User entered '08 Sep 2020 21:47'	System	09 Sep 2020 01:47:26

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:25
User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:25

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 02:20:36
User entered '10 Sep 2020 22:20'	System	11 Sep 2020 02:20:36

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	11 Sep 2020 19:49:11
User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:49:11

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 19:49:11
User entered '11 Sep 2020 15:49'	System	11 Sep 2020 19:49:11

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 03:16:03
User entered '12 Sep 2020 23:16'	System	13 Sep 2020 03:16:03

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 01:33:31
User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:31

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 06:55:53
User entered '16 Sep 2020 02:55'	System	16 Sep 2020 06:55:53

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 09:59:40
User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:40

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:52:44
User entered '17 Sep 2020 21:52'	System	18 Sep 2020 01:52:44

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 21:50:41
User entered 'None (0)'	System	18 Sep 2020 21:50:41

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 09:29:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 21:50:41
User entered '18 Sep 2020 17:50'	System	18 Sep 2020 21:50:41

US3512176

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:04:31
User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:31

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:17
User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:17

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:37:56
User entered 'No interference with activity (1)'	System	08 Sep 2020 02:37:56

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:37:56
User entered '07 Sep 2020 22:37'	System	08 Sep 2020 02:37:56

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:48:12
User entered '08 Sep 2020 21:48'	System	09 Sep 2020 01:48:12

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:40
User entered 'None (0)'	System	09 Sep 2020 22:25:40

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:40
User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:40

US3512176

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 11:04:46
User entered '06 Sep 2020 07:04'	System	06 Sep 2020 11:04:46

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:26
User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:26

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:38:14
User entered 'None (0)'	System	08 Sep 2020 02:38:14

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:38:14
User entered '07 Sep 2020 22:38'	System	08 Sep 2020 02:38:14

US3512176

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:48
User entered 'No (N)'	System	07 Sep 2020 02:12:48

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	07 Sep 2020 02:12:48
User entered '06 Sep 2020 22:12'	System	07 Sep 2020 02:12:48

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:38:19
User entered 'No (N)'	System	08 Sep 2020 02:38:19

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 02:38:19
User entered '07 Sep 2020 22:38'	System	08 Sep 2020 02:38:19

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 01:48:25
User entered 'No (N)'	System	09 Sep 2020 01:48:25

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:42
User entered 'No (N)'	System	09 Sep 2020 22:25:42

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 22:25:42
User entered '09 Sep 2020 18:25'	System	09 Sep 2020 22:25:42

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	11 Sep 2020 19:49:20
User entered 'No (N)'	System	11 Sep 2020 19:49:20

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 19:49:20
User entered '11 Sep 2020 15:49'	System	11 Sep 2020 19:49:20

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	13 Sep 2020 03:16:10
User entered 'No (N)'	System	13 Sep 2020 03:16:10

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	13 Sep 2020 03:16:10
User entered '12 Sep 2020 23:16'	System	13 Sep 2020 03:16:10

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	14 Sep 2020 02:31:46
User entered 'No (N)'	System	14 Sep 2020 02:31:46

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Sep 2020 02:31:46
User entered '13 Sep 2020 22:31'	System	14 Sep 2020 02:31:46

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 01:33:39
User entered 'No (N)'	System	15 Sep 2020 01:33:39

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 01:33:39
User entered '14 Sep 2020 21:33'	System	15 Sep 2020 01:33:39

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 06:56:04
User entered 'No (N)'	System	16 Sep 2020 06:56:04

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 09:59:51
User entered 'No (N)'	System	17 Sep 2020 09:59:51

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 09:59:51
User entered '17 Sep 2020 05:59'	System	17 Sep 2020 09:59:51

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 01:52:52
User entered 'No (N)'	System	18 Sep 2020 01:52:52

US3512176

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:25:29

US3512176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:25:29

US3512176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:25:29

US3512176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:25:29

US3512176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	08 Sep 2020 18:25:38

US3512176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:25:38

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:41

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:41

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:41

US3512176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:41

US3512176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:48

US3512176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:26:48

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:47:03

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	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: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:47:03

US3512176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:47:03

US3512176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:47:09

US3512176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 19:47:09

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	05 Nov 2020 15:12:03
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	05 Nov 2020 15:12:03

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:12'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '123'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:13:45
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:13:45

US3512176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:52
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[If No, reason not given](#)

Audit	User	Time (GMT)
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 dsicontinuation 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 dsicontinuation 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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:15:17
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:15:17

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:52'	Brenda Anderson (b) (4)	05 Nov 2020 15:15:55
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '10:15'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:22

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:16:18
	(b) (4)	

US3512176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:16:18

US3512176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:02:47

US3512176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:02:47

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:03:05

US3512176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:03:10

US3512176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:03:10

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:53:25

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:53:25

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:53:25

US3512176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:53:25

US3512176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:53:30

US3512176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 18:53:30

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:06:07
	(b) (4)	

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:06:07
	(b) (4)	

US3512176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:06:07

US3512176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:06:13

US3512176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:06:13

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:11
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 15:08:11

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:53'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.9' F	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '22'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Brenda Anderson (b) (4)	05 Nov 2020 15:08:49
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:08:49

US3512176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:09
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:29

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:09:29

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:05'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:29
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:09:34
	(b) (4)	

US3512176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:09:34

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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: '2020-11-16T15:44:35', 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: 26 Nov 2020 09:29:22

Have you been exposed to someone with 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: '2020-11-16T15:44:41', 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: 26 Nov 2020 09:29:22

[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: '2020-11-16T15:44:55', 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

US3512176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 20:25:10

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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 Oct 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: 26 Nov 2020 09:29:22

[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 Oct 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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 20:25:10

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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 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: 26 Nov 2020 09:29:22

[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 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: 26 Nov 2020 09:29:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:25:10
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 20:25:10

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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 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: 26 Nov 2020 09:29:22

[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 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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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'	System	19 Nov 2020 23:23:39
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: 26 Nov 2020 09:29:22

Have you been exposed to someone with 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'	System	19 Nov 2020 23:23:39
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

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'	System	23 Nov 2020 09:06:16
User entered 'No (N)'	System	23 Nov 2020 09:06:16

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

Have you been exposed to someone with 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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

[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

US3512176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	23 Nov 2020 18:58:57

US3512176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sheldon Warren (b) (4) (b) (4)	23 Nov 2020 18:58:57

US3512176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	23 Nov 2020 18:58:57

US3512176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	23 Nov 2020 18:58:57

US3512176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	23 Nov 2020 18:59:01

US3512176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:59:01

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:22

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:33:50
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:22

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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) (b) (4)	19 Nov 2020 13:33:58
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:45:05
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:45:05

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:22

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:05

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:22

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:45:05

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:49:10
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	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:45:47
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:50:43
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.9' F reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:50:43
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:29:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:45:47

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Date](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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 (2)

Generated On: 26 Nov 2020 09:29:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:29:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Date](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97' reason for change: Data Entry Error	Allison Crain (b) (4)	05 Nov 2020 15:14:56
User entered '97.' (non-conformant).	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 15:14:56
User entered empty.	System	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '98' F reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Vomiting](#)

Audit	User	Time (GMT)
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 (3)

Generated On: 26 Nov 2020 09:29:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:29:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 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: 26 Nov 2020 09:29:22

[Date](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	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: 26 Nov 2020 09:29:22

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:54:27
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:29:22

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 09:29:22

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 09:29:22

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	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: 26 Nov 2020 09:29:22

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	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: 26 Nov 2020 09:29:22

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:49:31
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:49:10

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Date of Test](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:52:45
	(b) (4)	

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:29:22

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:52:45

US3512176

Folder: Covid-19 Assessment 22 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:22

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:02:23

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (b) (4)	19 Nov 2020 13:34:46
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) (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Nov 2020 13:34:46
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:22

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09

US3512176

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:05:09
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
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) (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)	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)	05 Nov 2020 14:55:24

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:55:24

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	05 Nov 2020 14:55:24
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	05 Nov 2020 14:55:24

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:56'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Height (xxx.x)

Audit	User	Time (GMT)
User entered '60.25' in	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: 26 Nov 2020 09:29:22

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '96.1' kg	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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.9' F	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '22'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '130'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:17
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:01:17

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:28
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:28
	(b) (4)	

US3512176

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:29:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (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: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:01:45
	(b) (4)	

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:02:48

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:03:02

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:03:07

US3512176

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 15:03:12

US3512176

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:29:22

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:03:12
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

[Visit Date](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

[Physical Exam](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4)	05 Nov 2020 15:39:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 09:29:22

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 15:39:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:59'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Brenda Anderson (b) (4)	05 Nov 2020 15:40:54
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 15:40:54

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 15:41:06
	(b) (4)	

US3512176

Folder: Unscheduled 25 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 15:41:06
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:20:45

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[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)	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
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)	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)	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)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:22:46
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	Sheldon Warren (b) (4)	14 Sep 2020 17:22:46
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:22:17
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Sep 2020' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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)	21 Nov 2020 20:44:03
User entered 'None (NONE)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:48:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:22:17

US3512176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[Medically Attended AE 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 (2)

Generated On: 26 Nov 2020 09:29:22

[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)	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
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)	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)	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)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 10:00'	System	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
User entered '18 Sep 2020' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
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

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	23 Oct 2020 13:10:38
User entered '10:00' reason for change: Data Entry Error	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
User entered empty.	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
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
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	22 Sep 2020 19:49:42
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
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	14 Sep 2020 17:23:42

US3512176

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[Medically Attended AE 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 (3)

Generated On: 26 Nov 2020 09:29:22

[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)	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)	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
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) (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) (b) (4)	07 Oct 2020 16:51:01

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 10:00'	System	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020 10:00'	System	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

None

Audit	User	Time (GMT)
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) (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)	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 '1'	Sheldon Warren (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:25:20

US3512176

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Adverse event](#)

Audit	User	Time (GMT)
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)	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)	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
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) (b) (4)	07 Oct 2020 16:55:43
Coding entries removed.	Sheldon Warren (b) (4) (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) (b) (4)	07 Oct 2020 16:55:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Adverse event](#)

Audit	User	Time (GMT)
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). ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:45:55
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, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

None

Audit	User	Time (GMT)
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) (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)	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 '1'	Sheldon Warren (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 17:26:24

US3512176

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[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 (5)

Generated On: 26 Nov 2020 09:29:22

[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)	23 Sep 2020 05:40:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 05:40:57
Data point term sent to Coder	System	22 Sep 2020 19:51:46
User entered 'intermittent hives on face and neck'	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Sheldon Warren (b) (4)	23 Oct 2020 12:58:07
User entered 'No (N)'	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Sheldon Warren (b) (4)	23 Oct 2020 12:58:07
User entered '4 Oct 2020' reason for change: New Information	Sheldon Warren (b) (4)	07 Oct 2020 16:57:14
User entered '20 Sep 2020'	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sheldon Warren (b) (4)	23 Oct 2020 12:58:07
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 05:56:28
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'did not receive 2nd vaccine' (Site from System).	Sheldon Warren (b) (4)	07 Oct 2020 16:57:56
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Oct 2020 16:57:14
User entered '11:00' reason for change: Data Entry Error	Sheldon Warren (b) (4)	07 Oct 2020 16:57:14
User entered empty.	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 12:58:07
User entered '4 Oct 2020 11:00'	System	07 Oct 2020 16:57:14
User entered empty.	System	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 16:57:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 16:57:14
User entered 'Related (RELATED)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	07 Oct 2020 16:57:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:51:03
User entered empty.	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 16:57:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 16:57:14
User entered 'Related (RELATED)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	07 Oct 2020 16:57:14
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:51:03
User entered empty.	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[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 20:45:05
User entered 'None (NONE)'	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	23 Oct 2020 12:58:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:29:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 19:51:03

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[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)	11 Nov 2020 00:38:41
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 00:38:41
Data point term sent to Coder	System	05 Nov 2020 14:33:58
User entered 'intermittent hives (face and neck)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:35:51
User entered '08 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:36:18
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Oct 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:36:18
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:35:51
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[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 20:45:25
User entered 'None (NONE)'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:36:18
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:33:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:33:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:33:59
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:33:50
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:33:50
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:29:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:33:50

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[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)	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)	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)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[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) (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

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
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
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

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:37:25

US3512176

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Medically Attended AE 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 (8)

Generated On: 26 Nov 2020 09:29:22

[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)	05 Nov 2020 14:41:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:41:22
Data point term sent to Coder	System	05 Nov 2020 14:40:07
User entered 'intermittent fatigue'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:39:53
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:32
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:39:53
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:32
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:39:53
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:32
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[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) (b) (4)	21 Nov 2020 20:46:18
User entered 'None (NONE)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:39:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 14:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:39:32
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:39:32
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:39:32

US3512176

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:29:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:39:53

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Adverse event](#)

Audit	User	Time (GMT)
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

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52
	(b) (4)	

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[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) (b) (4)	21 Nov 2020 20:46:57
User entered 'Dose Delayed (DOSE DELAYED)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[None](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 14:41:52

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[Outcome](#)

Audit	User	Time (GMT)
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
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

US3512176

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:29:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

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: 26 Nov 2020 09:29:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:41:52

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:13:32

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERTENSION'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	29 Aug 2020 17:15:04

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPOTHYROIDISM'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '112'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1978'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANXIETY/FIBROMYALGIA'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1981'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	29 Aug 2020 17:16:58

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACID REFLUX'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
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) (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)	07 Oct 2020 17:00:08
User entered 'vitamin D deficiency' reason for change: Data Entry Error	Sheldon Warren (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)	29 Aug 2020 17:17:40

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2000'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	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: 26 Nov 2020 09:29:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHES'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:24:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 00:24:35
Data point term sent to Coder	System	29 Aug 2020 17:19:50
User entered 'FISH OIL'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'HIGH TRIGLYCERIDES'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1200'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
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) (b) (4)	07 Oct 2020 17:01:10
User entered 'mg (mg)' reason for change: Per Query Resolution	Sheldon Warren (b) (4) (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) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 17:00:58
User entered 'UNITS'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	29 Aug 2020 17:18:57

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[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)	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) (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) (b) (4)	08 Sep 2020 18:27:13

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'EVERY 2 hours' reason for change: New Information	Sheldon Warren (b) (4) (b) (4)	22 Sep 2020 19:52:23
User entered 'every 4-6 hours'	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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:52:23
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Sep 2020' reason for change: New Information	Sheldon Warren (b) (4)	22 Sep 2020 19:52:23
User entered empty.	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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal influenza'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'injection'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	15 Oct 2020 18:55:41

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	05 Nov 2020 14:29:03

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'intermittent hives'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	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: 26 Nov 2020 09:29:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'application'	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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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)	05 Nov 2020 14:30:27

US3512176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:29:22

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower back headache'	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: 26 Nov 2020 09:29:22

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:30:18
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) (b) (4)	19 Nov 2020 13:30:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:30:27
User entered empty.	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: 26 Nov 2020 09:29:22

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 13:30:18
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) (b) (4)	19 Nov 2020 13:30:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:30:27
User entered empty.	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: 26 Nov 2020 09:29:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:29:22

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:29:22

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	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: 26 Nov 2020 09:29:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 09:29:22

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:29:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:29:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:30:27

US3512176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:22

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Allison Crain (b) (4) (b) (4)	19 Nov 2020 13:53:45

US3512176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:22

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
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) (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.'	Taylor Johnson (b) (4)	21 Nov 2020 20:43:03
answered with 'data updated' (Site from DM).	(b) (4)	
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)	19 Nov 2020 13:57:32
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Allison Crain (b) (4)	19 Nov 2020 13:53:45

US3512176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:22

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: 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
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)	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)	19 Nov 2020 13:53:45