

US3512193 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:03:33

All time stamps listed in this document are displayed in GMT

US3512193

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:33:07

Generated On: 10 Jun 2021 08:03:33

[Participant ID](#)

US3512193

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

US3512193

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3512193

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3512193

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3512193

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Were any significant conditions reported?

Yes ☒
No ☐

US3512193

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1950
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1950
Start Year (derived)	1950
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512193

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512193

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3512193

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	BILATERAL PERIPHERAL VASCULAR DISEASE
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512193

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1969
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512193

Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	FORMER TOBACCO USE
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1964
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1964
Stop Year (derived)	1964

US3512193

Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	CHONDRODERMATITIS NODULARIS HELICIS
Start date (dd MMM yyyy)	25 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3512193

Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	18 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	18 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

US3512193

Folder: Screening

Form: Medical History (37)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	VARICOSE VEIN ABLATION X3
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3512193

Folder: Screening

Form: Medical History (38)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (39)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1969
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1969
Start Year (derived)	1969
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3512193

Folder: Screening

Form: Medical History (40)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (41)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (42)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (43)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (44)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Medical History (45)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

Condition	LEFT BICEP REPAIR
Start date (dd MMM yyyy)	18 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	18 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

US3512193

Folder: Screening

Form: Medical History (46)

Data signed: (b) (4) 08 Apr 2021 12:05:29

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:00
Height (<i>xxx.x</i>)	63.25 in
Weight (<i>xxx.x</i>)	132.4 lb
BMI (<i>xxx.x</i>)	23.31722 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512193

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3512193

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*) 2 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1990

Date of surgery unknown False

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

Date of last menstruation unknown False

US3512193

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	PARTICIPANT PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER (COSTCO WEEKLY, CVS, GYM, PLANNING A TRIP TO NORTH CAROLINA IN LATE SEPTEMBER)

US3512193

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 189003

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 ☒

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:00
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:13
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3512193

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

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.

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 11:42 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 11:42

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

US3512193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	10:42 (24 HR)
Collection date and time (derived)	2 SEP 2020 10:42

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	2 SEP 2020 11:05
Nasopharyngeal Swab 2	No		

US3512193

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:57

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

96.6 °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

02 SEP 2020 12:18

PC Open Date & Time

02 SEP 2020 12:02

PC Close Date & Time

02 SEP 2020 14:32

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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 97.6 °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	02 SEP 2020 17:31
PC Open Date & Time	02 SEP 2020 15:27
PC Close Date & Time	03 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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):

PC Time Stamp

04 SEP 2020 14:14

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 14:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 13:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 13:52

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

02 SEP 2020 12:20

PC Open Date & Time

02 SEP 2020 12:02

PC Close Date & Time

02 SEP 2020 14:32

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

02 SEP 2020 17:33

PC Open Date & Time

02 SEP 2020 15:27

PC Close Date & Time

03 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

03 SEP 2020 14:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

04 SEP 2020 14:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 14:25

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

07 SEP 2020 13:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 13:52

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 12:20
PC Open Date & Time	02 SEP 2020 12:02
PC Close Date & Time	02 SEP 2020 14:32

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 17:34
PC Open Date & Time	02 SEP 2020 15:27
PC Close Date & Time	03 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 14:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:58
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 14:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 3165

EAB) (1725)

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 3165

EAB) (1725)

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:53
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3512193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:24
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 11:33
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3512193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

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.

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 11:02

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

US3512193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	10:44 (24 HR)
Collection date and time (derived)	2 OCT 2020 10:44

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:34	2 OCT 2020 10:34
Nasopharyngeal Swab 2	No		

US3512193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 11:34

PC Open Date & Time

02 OCT 2020 11:22

PC Close Date & Time

02 OCT 2020 13:52

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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 97.0 °F

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

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

PC Time Stamp	02 OCT 2020 17:08
PC Open Date & Time	02 OCT 2020 14:47
PC Close Date & Time	03 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 09:28

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 12:08

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

97.4 °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

06 OCT 2020 12:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

97.2 °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

07 OCT 2020 17:02

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 14:12

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

02 OCT 2020 11:36

PC Open Date & Time

02 OCT 2020 11:22

PC Close Date & Time

02 OCT 2020 13:52

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

02 OCT 2020 17:08

PC Open Date & Time

02 OCT 2020 14:47

PC Close Date & Time

03 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

03 OCT 2020 12:51

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

05 OCT 2020 09:29

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 12:08

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

07 OCT 2020 17:02

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 14:12

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 11:37
PC Open Date & Time	02 OCT 2020 11:22
PC Close Date & Time	02 OCT 2020 13:52

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 17:09
PC Open Date & Time	02 OCT 2020 14:47
PC Close Date & Time	03 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

133 of 3165

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:52
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

135 of 3165

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 09:29
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:09
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

139 of 3165

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:48
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

141 of 3165

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 17:44
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 14:13
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3512193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 NOV 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 11:45
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

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.

US3512193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 NOV 2020

Collection time (00:00-23:59)

12:12 (24 HR)

Collection date and time (derived)

17 NOV 2020 12:12

US3512193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:58

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 NOV 2020 13:04:59
Patient Cloud Open Date & Time	02 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
156 of 3165	

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 NOV 2020 13:18:40
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 NOV 2020 12:00:05
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 NOV 2020 12:02:57
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

28 NOV 2020 08:27:04

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 08:52:52
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 16:01:23

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 10:55:29

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 17:01:28

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 12:13:36
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 12:54:44

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 10:01:58

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 09:03:13

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 09:55:38

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 11:54:39

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:07:05
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 17:05:54

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 23:00:05

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 17:55:44

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 15:32:15
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 10:30:23

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 12:06:40

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 17:59:33

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 10:07:22

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 16:35:30

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 18:00:53

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 15:15:58

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2021 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	17 AUG 2021 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	19 NOV 2021 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	23 NOV 2021 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	22 APR 2022 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	26 APR 2022 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2022 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	16 AUG 2022 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	26 AUG 2022 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	30 AUG 2022 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

Patient Cloud Open Date & Time	21 OCT 2022 00:01
----------------------------------------------------	-------------------

Patient Cloud Close Date & Time	25 OCT 2022 23:59
-----------------------------------------------------	-------------------

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3512193

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:03:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 23:01:12

US3512193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 20:00:39

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 20:00:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:29:35

Generated On: 10 Jun 2021 08:03:33

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

Visit date (dd MMM yyyy)	31 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:29:35

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3512193

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:29:35

Generated On: 10 Jun 2021 08:03:33

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.

US3512193

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:29:35

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	10:18 (24 HR)
Collection date and time (derived)	31 MAR 2021 10:18

US3512193

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:29:35

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:04:39

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512193

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:04:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512193

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 10 Jun 2021 08:03:33

Date of Contact	23 OCT 2020
Time of Contact	10:00
Date and Time of Contact (derived)	23 OCT 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		366 of 3165
EAB) (1725)		

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	True	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

Symptom Day

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

Date	27 OCT 2020
------	-------------

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

O2 Saturation	85 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 3165

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 21:34:55

Generated On: 10 Jun 2021 08:03:33

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 OCT 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3512193

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:34
Height (xxx.x)	63.25 in
Weight (xxx.x)	132.4 lb
Temperature (xxx.x)	100.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512193

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

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.

US3512193

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 OCT 2020

US3512193

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

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

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

US3512193

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

Form: Unblinding

Data signed: (b) (4) 14 Apr 2021 16:44:38

Generated On: 10 Jun 2021 08:03:33

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3512193

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

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

Collection date (dd MMM yyyy)	22 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:45 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 JAN 2021 10:45
------------------------------------	-------------------

US3512193

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:35
Collection Date and Time (derived)	22 JAN 2021 10:35

US3512193

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:33:07

Generated On: 10 Jun 2021 08:03:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID	USA-US065-2020-MRNA-1273-P30 1000002
Adverse event	ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SUBJECT NOW HAS ONGOING ATRIAL FIBRILLATION, NO LONGER A SERIOUS ADVERSE EVENT.

Narrative

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

PT IN CONVALESCENT PERIOD
STARTING WITH ILLNESS VISIT
ON 23 OCT 2020. 27-OCT-2020 PT
CALLED SITE WITH PULSE OX
OF 91% SOON AFTER WAKING.
IT WAS RECOMMENDED THAT
SHE GET UP AND MOVE
AROUND AND REPEAT HER
PULSE OX. AT 12:21 PM PT
REPORTED A PULSE OX OF 85%.
SUBJECT ALSO HAD
SHORTNESS OF BREATH AND
TERRIBLE HEADACHE. DR.
(b) (6) (SUB-I) RECOMMENDED
THAT SHE CONTACT HER PCP
AND INFORM THEM OF HER
SYMPTOMS. PT WAS
INSTRUCTED THAT IF PCP WAS
NOT AVAILABLE TO SEEK
MEDICAL ATTENTION. PT HAD
COVID TEST AT HOSPITAL
NEGATIVE.. PT DIAGNOSISED
WITH ATRIAL FIBRILLATION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID

Adverse event

WORSENERD INTERMITTENT
SINUSITIS

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)

2 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

406 of 3165

EAB) (1725)

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID	
Adverse event	ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID

Adverse event

RIGHT MIDDLE TOE FRACTURE

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)

26 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

410 of 3165

EAB) (1725)

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 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)

5 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

412 of 3165

EAB) (1725)

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

AEID

Adverse event

ACTINIC KERATOSIS (RIGHT
AND LEFT MID-CHEEK
FURROW, LEFT
PALPEBROMALAR GROOVE,
RIGHT LOWER VERMILLION
BORDER)

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 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

PRODUCTION RELEASE (v12.003

414 of 3165

EAB) (1725)

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
<hr/>	
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
<hr/>	
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
<hr/>	
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
<hr/>	
PRODUCTION RELEASE (v12.003 EAB) (1725)	415 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 26 Mar 2021 14:25:44

Generated On: 10 Jun 2021 08:03:33

Admitted to ICU Derived (CSA Programming Field Only)

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:33:07

Generated On: 10 Jun 2021 08:03:33

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

Yes ☒

No ☐

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

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication LYOTHYRONINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 5

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

420 of 3165

EAB) (1725)

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 60

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

422 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication FLUTICASONE NASAL SPRAY

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 100

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

424 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication AREDS 2

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA/MACULAR
DEGENERATION

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication CALCIUM WITH VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1200/1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

430 of 3165

EAB) (1725)

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication RESVERATROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

434 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication OMEGA 3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

436 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☒
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

438 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication B COMPLEX PLUS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

440 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

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

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

442 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 220

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

446 of 3165

EAB) (1725)

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 600

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

448 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication TRIAMCINOLONE 0.1%

Prophylaxis Yes ☐
No ☒

Indication CONTACT DERMATITIS
BILATERAL ARM

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATIONS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

450 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 MAR 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT URINARY
TRACT INFECTION

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

452 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

454 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 220

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

456 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

458 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

460 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

462 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

464 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

466 of 3165

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Feb 2021 21:25:27

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 21:33:07

Generated On: 10 Jun 2021 08:03:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 OCT 2020	ECHOCARDIOGRAM	Adverse Event	
29 OCT 2020	CARDIOVERSION	Adverse Event	
13 NOV 2020	CARDIOVERSION	Adverse Event	
9 DEC 2020	CRYOBALLOON ABLATION	Adverse Event	
23 FEB 2021	CRYOTHERAPY	Adverse Event	

US3512193

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:03:33

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3512193

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:03:33

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 ☐

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US065-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US065-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/NOV/2020 19:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US065-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 16:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US065-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 21:34:56

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US065-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/DEC/2020 15:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3512193 (Prod: Jacksonville Center for Clinical Research Center)

US3512193

Form: Participant Creation

Generated On: 10 Jun 2021 08:03:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered 'US3512193'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:04:50

US3512193

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 16:00:25

US3512193

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:04:51

US3512193

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	02 Sep 2020 16:00:25

US3512193

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'SCRN'	System	02 Sep 2020 16:00:25

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered (b) (6) 1943'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:04:52

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '77'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'YEARS'	System	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '77'	System	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Female (F)'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'I'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 16:00:53

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Sep 2020'	System	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Amendment 3 (3)'	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:01:08

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:04:51

US3512193

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'I'	System	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:03:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 16:07:42

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:50
Data point term sent to Coder	System	02 Sep 2020 17:27:50
User entered 'SINUSITIS'	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2015'	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2015'	System	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2015'	System	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:26:58

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
Data point term sent to Coder	System	02 Sep 2020 17:27:50
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2010'	System	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2010'	System	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:27:35

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
Data point term sent to Coder	System	02 Sep 2020 17:28:52
User entered 'CONSTIPATION'	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1950'	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1950'	System	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1950'	System	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:27:51

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:31
Data point term sent to Coder	System	02 Sep 2020 17:28:51
User entered 'HEMORRHOIDS'	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2010'	System	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2010'	System	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:28:10

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Recurrent urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:38:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:38:00
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	06 Oct 2020 03:46:41
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	02 Oct 2020 23:43:55
' answered with 'Ciprofloxacin added to con med eCRF.' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	02 Oct 2020 09:27:19
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:29:51
Data point term sent to Coder	System	02 Sep 2020 17:28:54
User entered 'INTERMITTENT URINARY TRACT INFECTIONS'	Allison Crain (b) (4)	02 Sep 2020 17:28:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

550 of 3165

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2015'	Allison Crain (b) (4)	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2015'	System	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2015'	System	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:28:49

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:46
Data point term sent to Coder	System	02 Sep 2020 17:29:55
User entered 'GLAUCOMA'	Allison Crain (b) (4)	02 Sep 2020 17:29:05
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2014'	Allison Crain (b) (4)	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2014'	System	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2014'	System	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:29:05

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:30:46
Data point term sent to Coder	System	02 Sep 2020 17:29:55
User entered 'BILATERAL CATARACTS'	Allison Crain (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2002'	Allison Crain (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 17:30:54
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:30:54
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	02 Sep 2020 17:29:37
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2002'	Allison Crain (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2002'	System	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2002'	System	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2002'	System	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2002'	System	02 Sep 2020 17:29:37

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder	System	02 Sep 2020 17:31:56
User entered 'BILATERAL CATARACTS REMOVAL'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2002'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2002'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2002'	System	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2002'	System	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2002'	System	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2002'	System	02 Sep 2020 17:31:18

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
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)	02 Sep 2020 17:32:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:55
Data point term sent to Coder	System	02 Sep 2020 17:31:57
User entered 'NEARSIGHTED'	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1953'	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1953'	System	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1953'	System	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:31:38

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder	System	02 Sep 2020 17:31:57
User entered 'FARSIGHTED'	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1953'	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1953'	System	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1953'	System	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:31:52

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:33:44
Data point term sent to Coder	System	02 Sep 2020 17:33:00
User entered 'MACULAR DEGENERATION'	Allison Crain (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2017'	Allison Crain (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2017'	System	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2017'	System	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:32:10

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Retinal therapeutic procedures, PT: Retinal operation, LLT: Retinal operation - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 20:19:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 20:19:48
Data point term sent to Coder	System	02 Sep 2020 17:34:01
User entered 'BILATERAL RETINAL REPAIR'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1998'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1998'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1998'	System	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1998'	System	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1998'	System	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1998'	System	02 Sep 2020 17:33:25

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Retinal tear - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:31:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:31:47
Data point term sent to Coder	System	03 Sep 2020 22:29:50
User entered 'BILATERAL RETINAL TEARS'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1998'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1998'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1998'	System	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1998'	System	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1998'	System	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1998'	System	03 Sep 2020 22:29:35

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:34:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:34:46
Data point term sent to Coder	System	02 Sep 2020 17:34:02
User entered 'MIGRAINES'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1973'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:11:31
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:11:31
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1973'	System	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1973'	System	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	05 Nov 2020 13:11:31
User entered 'Jan 1990'	System	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	05 Nov 2020 13:11:31
User entered '1990'	System	02 Sep 2020 17:33:55

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 03:47:00
Query 'Per DM CLR: Please note that there is no Con Allison Crain Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Subject does not take or use an inhaler for this condition.' (Site from DM).	(b) (4) (b) (4)	02 Oct 2020 15:40:44
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:31:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:35:51
Data point term sent to Coder	System	02 Sep 2020 17:35:02
User entered 'EXERCISE INDUCED ASTHMA'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2013'	Allison Crain (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2013'	System	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2013'	System	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:11

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:35:52
Data point term sent to Coder	System	02 Sep 2020 17:35:03
User entered 'ACNE'	Allison Crain (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1960'	Allison Crain (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1960'	System	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1960'	System	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:24

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:35:52
Data point term sent to Coder	System	02 Sep 2020 17:35:03
User entered 'ECZEMA'	Allison Crain (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN May 2020'	Allison Crain (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'May 2020'	System	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:34:42

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Squamous cell carcinoma of skin, LLT: Squamous cell carcinoma of skin - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:36:48
Data point term sent to Coder	System	02 Sep 2020 17:36:04
User entered 'SQUAMOUS CELL SKIN CANCER'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	02 Sep 2020 17:35:05

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma face - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:35:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:35:50
Data point term sent to Coder	System	19 Nov 2020 17:24:26
Coding entries removed.	Brenda Anderson (b) (4)	19 Nov 2020 17:23:44
User entered 'BASAL CELL SKIN CANCER face' reason for change: New Information	Brenda Anderson (b) (4)	19 Nov 2020 17:23:44
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:36:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:36:47
Data point term sent to Coder	System	02 Sep 2020 17:36:04
User entered 'BASAL CELL SKIN CANCER'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2014'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2014'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2014'	System	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2014'	System	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2014'	System	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2014'	System	02 Sep 2020 17:35:26

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
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)	02 Sep 2020 17:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:37:50
Data point term sent to Coder	System	02 Sep 2020 17:37:05
User entered 'OSTEOARTHRITIS OF BILATERAL HANDS AND KNEES'	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2013'	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2013'	System	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2013'	System	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:36:25

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:37:50
Data point term sent to Coder	System	02 Sep 2020 17:37:05
User entered 'OSTEOPOROSIS'	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2013'	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2013'	System	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2013'	System	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:36:37

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:37:51
Data point term sent to Coder	System	02 Sep 2020 17:37:05
User entered 'BACK PAIN'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2010'	System	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2010'	System	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	02 Sep 2020 17:36:50

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Spinal laminectomy - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 16:34:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 16:34:46
Data point term sent to Coder	System	08 Sep 2020 16:33:18
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of LAMINECTOMY spinal and one of Spinal fusion surgery etc.' (Site from System).	System	08 Sep 2020 16:32:56
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of LAMINECTOMY spinal and one of Spinal fusion surgery etc.' answered with 'UPDATED' (Site from System).	Allison Crain (b) (4)	08 Sep 2020 16:32:56
User entered 'SPINAL LAMINECTOMY' reason for change: Data Entry Error	Allison Crain (b) (4)	08 Sep 2020 16:32:22
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of LAMINECTOMY spinal and one of Spinal fusion surgery etc.' (Site from System).	Coder Import (b) (4)	08 Sep 2020 13:32:40
Data point term sent to Coder	System	03 Sep 2020 22:34:00
Coding entries removed.	Allison Crain (b) (4)	03 Sep 2020 22:33:31
User entered 'LAMINECTOMY AND FUSION' reason for change: Data Entry Error	Allison Crain (b) (4)	03 Sep 2020 22:33:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Spinal operation - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:43:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:43:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

730 of 3165

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Sep 2020 17:43:16
User entered 'LUMBAR SPINE SURGERY' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:42:55
User entered 'DUPUYTREN'S CONTRACTURE BILATERAL HANDS'	Allison Crain (b) (4)	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 17:42:55
User entered 'UN UNK 2016' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:42:55
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 17:42:19
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:42:19
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 17:42:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:42:55
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:42:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 17:42:19
User entered empty.	System	02 Sep 2020 17:42:19
	Allison Crain (b) (4)	02 Sep 2020 17:42:19
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:42:55
User entered empty.	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:42:19
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	02 Sep 2020 17:42:55
User entered empty.	System	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	02 Sep 2020 17:42:55
User entered empty.	System	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	02 Sep 2020 17:42:55
User entered empty.	System	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	02 Sep 2020 17:42:55
User entered empty.	System	02 Sep 2020 17:42:19

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Dupuytren's contracture, LLT: Dupuytren's contracture - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 09:45:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 09:45:39
Data point term sent to Coder	System	02 Sep 2020 17:44:17
User entered 'DUPUTREN'S CONTRACTURE BILATERAL HANDS'	Allison Crain (b) (4)	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	03 Sep 2020 22:30:02
User entered 'UN UNK 2000' reason for change: Data Entry Error	Allison Crain (b) (4)	03 Sep 2020 22:30:02
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4) System	02 Sep 2020 17:43:20
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:43:20
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:30:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4)	03 Sep 2020 22:30:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Sep 2020 17:43:20
	Allison Crain (b) (4)	02 Sep 2020 17:43:20
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2000'	System	03 Sep 2020 22:30:02
User entered empty.	System	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2000'	System	03 Sep 2020 22:30:02
User entered empty.	System	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:43:20

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
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)	02 Sep 2020 17:45:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:45:55
Data point term sent to Coder	System	02 Sep 2020 17:44:19
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:43:36

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:46:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:46:43
Data point term sent to Coder	System	02 Sep 2020 17:45:20
User entered 'CANCER OF THE LEFT BREAST'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:44:37

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:46:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:46:43
Data point term sent to Coder	System	02 Sep 2020 17:45:20
User entered 'BILATERAL MASTECTOMY'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:45:05

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:48
Data point term sent to Coder	System	02 Sep 2020 17:46:23
User entered 'HYPERTENSION'	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2014'	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2014'	System	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2014'	System	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:45:30

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per DM CLR: Please note this condition overlaps with MH#30 Varicose Veins, which is a form of Peripheral Vascular Disease. Please review and reconcile Med History entries and update Med History eCRF so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:47:22
Query 'Per DM CLR: Please note this condition overlaps with MH#30 Varicose Veins, which is a form of Peripheral Vascular Disease. Please review and reconcile Med History entries and update Med History eCRF so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'Bilateral Peripheral Vascular Disease will remain and MH#30 will be inactivated so that there is no overlap or duplicate data per query.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 23:51:58
User opened query 'Per DM CLR: Please note this condition overlaps with MH#30 Varicose Veins, which is a form of Peripheral Vascular Disease. Please review and reconcile Med History entries and update Med History eCRF so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:33:13
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 20:28:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 20:28:09
Data point term sent to Coder	System	02 Sep 2020 17:47:26
User entered 'BILATERAL PERIPHERAL VASCULAR DISEASE' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:46:30
Data point term sent to Coder	System	02 Sep 2020 17:46:24
User entered 'PERIPHERAL VASCULAR DISEASE'	Allison Crain (b) (4)	02 Sep 2020 17:45:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

791 of 3165

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	02 Sep 2020 17:46:01
User entered 'UN UNK 1993' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:46:01
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 17:45:52
User entered 'UN UNK 199' (non-conformant).	Allison Crain (b) (4)	02 Sep 2020 17:45:52
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 17:46:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:46:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:46:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 17:45:52
User entered empty.	System	02 Sep 2020 17:45:52
	Allison Crain (b) (4)	02 Sep 2020 17:45:52
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1993'	System	02 Sep 2020 17:46:01
User entered empty.	System	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1993'	System	02 Sep 2020 17:46:01
User entered empty.	System	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:45:52

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:47:49
Data point term sent to Coder	System	02 Sep 2020 17:47:26
User entered 'DEPRESSION'	Allison Crain (b) (4)	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1969' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	03 Sep 2020 22:36:19
User entered 'UN UNK 1974'	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:47:23
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1969'	System	03 Sep 2020 22:36:19
User entered 'Jan 1974'	System	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1969'	System	03 Sep 2020 22:36:19
User entered '1974'	System	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	02 Sep 2020 17:47:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Haematological and lymphoid tissue therapeutic procedures, HLT: Lymphoid tissue therapeutic procedures, PT: Lymphadenectomy, LLT: Lymph node excision - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 22:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 22:34:51
Data point term sent to Coder	System	02 Sep 2020 17:48:29
User entered 'LEFT UNDERARM LYMPH NODE REMOVAL'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:48:23

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
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)	02 Sep 2020 17:50:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:50:51
Data point term sent to Coder	System	02 Sep 2020 17:49:31
User entered 'BILATERAL TUBAL LIGATION'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1990'	System	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1990'	System	02 Sep 2020 17:48:53

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:51:54
Data point term sent to Coder	System	02 Sep 2020 17:50:33
User entered 'FORMER TOBACCO USE'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1960'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1964'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1960'	System	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1960'	System	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1964'	System	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1964'	System	02 Sep 2020 17:49:36

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Perichondritis, LLT: Chondrodermatitis nodularis chronica heliis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 06:24:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 06:24:39
Data point term sent to Coder	System	03 Sep 2020 22:31:56
User entered 'CHONDRODERMATITIS NODULARIS HELICIS'	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '25 Aug 2020'	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Aug 2020'	System	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:30:55

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:51
Data point term sent to Coder	System	08 Sep 2020 16:34:21
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	08 Sep 2020 16:33:33
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'UPDATED' (Site from System).	Allison Crain (b) (4)	08 Sep 2020 16:33:33
User entered 'LEFT ROTATOR CUFF REPAIR' reason for change: Data Entry Error	Allison Crain (b) (4)	08 Sep 2020 16:33:25
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	07 Sep 2020 21:43:29
Data point term sent to Coder	System	03 Sep 2020 22:32:57
User entered 'LEFT ROTATOR CUFF AND BICEP REPAIR'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '18 Dec 2018'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '18 Dec 2018'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Dec 2018'	System	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Dec 2018'	System	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	03 Sep 2020 22:32:52

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Venous therapeutic procedures, PT: Varicose vein operation, LLT: Varicose vein operation - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 08:47:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 08:47:35
Data point term sent to Coder	System	03 Sep 2020 22:35:01
User entered 'VARICOSE VEIN ABLATION X3'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	03 Sep 2020 22:34:18

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:36:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:36:52
Data point term sent to Coder	System	03 Sep 2020 22:36:02
User entered 'INSOMNIA'	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2010'	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2010'	System	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2010'	System	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:35:27

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:47:42
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	Allison Crain (b) (4)	02 Oct 2020 15:41:39
' answered with 'Subject is not being treated. This has ended.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	02 Oct 2020 09:35:30
' (Site from DM).		
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 22:36:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 22:36:03
User entered 'BIPOLAR DISORDER'	Allison Crain (b) (4)	03 Sep 2020 22:35:58
	(b) (4)	

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1969'	Allison Crain (b) (4)	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2015'	Allison Crain (b) (4)	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 1969'	System	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '1969'	System	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2015'	System	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (39)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2015'	System	03 Sep 2020 22:35:58

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:44:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:44:49
Data point term sent to Coder	System	19 Nov 2020 17:24:26
Coding entries removed.	Brenda Anderson (b) (4)	19 Nov 2020 17:24:11
User entered 'CONTACT DERMATITIS bilateral arms' reason for change: New Information	Brenda Anderson (b) (4)	19 Nov 2020 17:24:11
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:38:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:38:49
Data point term sent to Coder	System	03 Sep 2020 22:38:08
User entered 'CONTACT DERMATITIS'	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN Mar 2020'	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Mar 2020'	System	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (40)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:38:08

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
Data point term sent to Coder	System	03 Sep 2020 22:40:10
User entered 'HYPONATREMIA'	Allison Crain (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN Jan 2020'	Allison Crain (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2020'	System	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (41)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:39:32

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Oesophagitis, LLT: Esophagitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
Data point term sent to Coder	System	03 Sep 2020 22:40:10
User entered 'ESOPHAGITIS'	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2018'	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2018'	System	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (42)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:39:52

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 22:40:50
Data point term sent to Coder	System	03 Sep 2020 22:40:10
User entered 'GASTRITIS'	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2018'	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2018'	System	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (43)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered empty.	System	03 Sep 2020 22:40:05

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:34:47
Data point term sent to Coder	System	08 Sep 2020 16:33:17
User entered 'SPINAL FUSION'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Jan 2016'	System	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (44)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2016'	System	08 Sep 2020 16:32:39

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Muscle therapeutic procedures, PT: Muscle operation, LLT: Muscle operation - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 16:35:51
Data point term sent to Coder	System	08 Sep 2020 16:35:23
User entered 'LEFT BICEP REPAIR'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '18 Dec 2018'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '18 Dec 2018'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Dec 2018'	System	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Dec 2018'	System	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (45)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2018'	System	08 Sep 2020 16:34:38

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 14:10:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 14:10:02
Data point term sent to Coder	System	06 Apr 2021 14:08:58
User closed query 'DM-Coding: for term BOTOX FACIAL INJECTION (TEETH GRINDING), Please split diagnosis and procedure to report each event separately, example: 1) BOTOX FACIAL INJECTION 2) TEETH GRINDING etc. ' (Site from System).	System	06 Apr 2021 14:08:33
Query 'DM-Coding: for term BOTOX FACIAL INJECTION (TEETH GRINDING), Please split diagnosis and procedure to report each event separately, example: 1) BOTOX FACIAL INJECTION 2) TEETH GRINDING etc. ' answered with 'updated' (Site from System).	Allison Crain (b) (4)	06 Apr 2021 14:08:33
User entered 'BOTOX FACIAL INJECTION' reason for change: Data Entry Error	Allison Crain (b) (4)	06 Apr 2021 14:08:08
User opened query 'DM-Coding: for term BOTOX FACIAL INJECTION (TEETH GRINDING), Please split diagnosis and procedure to report each event separately, example: 1) BOTOX FACIAL INJECTION 2) TEETH GRINDING etc. ' (Site from System).	Coder Import (b) (4)	02 Apr 2021 08:15:21
Data point term sent to Coder	System	01 Apr 2021 20:57:29
User entered 'botox facial injection (teeth grinding)'	Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User entered 'un Mar 2020'	Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User entered '0'	Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User entered 'un Mar 2020'	(b) (4) Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:05:29
User entered '0'	Sheldon Warren (b) (4)	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Mar 2020'	System	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'Mar 2020'	System	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Medical History (46)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2020'	System	01 Apr 2021 20:56:32

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:00'	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '2 Sep 2020 10:00'	System	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '63.25' in	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:21:15
	(b) (4)	
DataPoint set to visible.	System	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '132.4' lb	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:21:15
DataPoint set to visible.	(b) (4) System	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered '23.31722'	System	02 Sep 2020 17:21:15
DataPoint set to visible.	System	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'kg/m2'	System	02 Sep 2020 17:21:15
DataPoint set to visible.	System	02 Sep 2020 16:01:16

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'bpm'	System	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'breaths/min'	System	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'mmHg'	System	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	Allison Crain (b) (4)	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User entered 'mmHg'	System	02 Sep 2020 17:21:15

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07

US3512193

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07

US3512193

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 16:01:33

US3512193

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 16:01:33

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:23:07
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:22:25
	(b) (4)	

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'UN UNK 1990' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:23:07
User entered empty.	(b) (4)	
	Allison Crain (b) (4)	02 Sep 2020 17:22:25
	(b) (4)	

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4)	02 Sep 2020 17:23:07
User entered 'UN UNK 1990'	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:03:33

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:22:25

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'I'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'I'	Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:45:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'PARTICIPANT PLANS ON ROUTINELY GOING TO PLACES WHERE PEOPLE GATHER (COSTCO WEEKLY, CVS, GYM, PLANNING A TRIP TO NORTH CAROLINA IN LATE SEPTEMBER)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:25:41

US3512193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 16:02:01

US3512193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:45:34
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 16:02:01

US3512193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	02 Sep 2020 16:02:01

US3512193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'VISIT1'	System	02 Sep 2020 16:02:01

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 15:04:43

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '189003'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 15:04:43

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 15:04:43

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:02:20

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:02:20

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:02:20

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:02:20

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:02:20

US3512193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 17:10:23
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 04:51:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:51:29

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:00'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Sep 2020 10:00'	System	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98.3' F	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Oral (Oral)'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '61'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'bpm'	System	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '14'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'breaths/min'	System	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '139'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '75'	Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:05

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '12:13'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Sep 2020 12:13'	System	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Re-query: Assessment is required for out of range values. Please re-assess out of range temperature value if CS or NCS and report an AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:52:48
Query 'Re-query: Assessment is required for out of range values. Please re-assess out of range temperature value if CS or NCS and report an AE if appropriate.' answered with 'This query is a system error per monitor (b) (6) (Site from DM).	Allison Crain (b) (4)	02 Oct 2020 15:23:33
User opened query 'Re-query: Assessment is required for out of range values. Please re-assess out of range temperature value if CS or NCS and report an AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:56
User closed query 'Per CDM: Please assess out of range value if CS or NCS and report an AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:01:56
Query 'Per CDM: Please assess out of range value if CS or NCS and report an AE as appropriate.' answered with 'per monitor respond confirm as is' (Site from DM).	Brenda Anderson (b) (4)	28 Sep 2020 19:43:58
User opened query 'Per CDM: Please assess out of range value if CS or NCS and report an AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:46:09
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 09:46:02
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirmed as is. Answered per monitor (b) (6) (Site from System).	Allison Crain (b) (4)	24 Sep 2020 13:16:30
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:25:32

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.6' F	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '60'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'bpm'	System	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '14'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'breaths/min'	System	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '147'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '84'	Allison Crain (b) (4)	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Sep 2020 17:51:50

US3512193

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 16:07:28

US3512193

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 16:07:28

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '11:42'	Allison Crain (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Sep 2020 11:42'	System	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Right Arm (RIGHT ARM)'	Allison Crain (b) (4)	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'ONCE'	System	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 16:16:38

US3512193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:52:04

US3512193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:52:04

US3512193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:42'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:52:04

US3512193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Sep 2020 10:42'	System	02 Sep 2020 17:52:04

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '11:05'	Allison Crain (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Sep 2020 11:05'	System	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered empty.	System	02 Sep 2020 17:52:17

US3512193

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 17:52:24

US3512193

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	02 Sep 2020 17:52:24

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:18:06', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '49208046-7c97-494f-ab2e-857944ae9f44' User entered 'Yes (Y)'	System	02 Sep 2020 16:18:46
	System	02 Sep 2020 16:18:46

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:18:17', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '49208046-7c97-494f-ab2e-857944ae9f44' User entered '96.6'	System	02 Sep 2020 16:18:46
	System	02 Sep 2020 16:18:46

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:18:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '49208046-7c97-494f-ab2e-857944ae9f44' User entered 'No (N)'	System	02 Sep 2020 16:18:46
	System	02 Sep 2020 16:18:46

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:18:43', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '49208046-7c97-494f-ab2e-857944ae9f44' User entered '02 Sep 2020 12:18'	System	02 Sep 2020 16:18:46
	System	02 Sep 2020 16:18:46

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 14:32'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:30:55', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '66d4ba85-1906-4087-b26d-14e829865464' User entered 'Yes (Y)'	System	02 Sep 2020 21:31:48
	System	02 Sep 2020 21:31:48

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:31:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '66d4ba85-1906-4087-b26d-14e829865464' User entered '97.6'	System	02 Sep 2020 21:31:48
	System	02 Sep 2020 21:31:48

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:31:29', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '66d4ba85-1906-4087-b26d-14e829865464' User entered 'No (N)'	System	02 Sep 2020 21:31:48
	System	02 Sep 2020 21:31:48

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:31:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '66d4ba85-1906-4087-b26d-14e829865464' User entered '02 Sep 2020 17:31'	System	02 Sep 2020 21:31:48
	System	02 Sep 2020 21:31:48

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 15:27'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 2'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:02:37', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '584c59f1-a32e-4e8f-95d6-59d795a3c107' User entered 'Yes (Y)'	System	03 Sep 2020 18:03:24
	System	03 Sep 2020 18:03:24

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:02:55', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '584c59f1-a32e-4e8f-95d6-59d795a3c107' User entered '97.1'	System	03 Sep 2020 18:03:24
	System	03 Sep 2020 18:03:24

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '584c59f1-a32e-4e8f-95d6-59d795a3c107' User entered 'No (N)'	System	03 Sep 2020 18:03:24
	System	03 Sep 2020 18:03:24

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '584c59f1-a32e-4e8f-95d6-59d795a3c107' User entered '03 Sep 2020 14:03'	System	03 Sep 2020 18:03:24
	System	03 Sep 2020 18:03:24

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 3'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:14:16', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0f2ca00e-cd75-4ea7-b803-4ad2cc0dc8a7' User entered 'Yes (Y)'	System	04 Sep 2020 18:14:50
	System	04 Sep 2020 18:14:50

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:14:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0f2ca00e-cd75-4ea7-b803-4ad2cc0dc8a7' User entered '97.8'	System	04 Sep 2020 18:14:50
	System	04 Sep 2020 18:14:50

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:14:34', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0f2ca00e-cd75-4ea7-b803-4ad2cc0dc8a7'	System	04 Sep 2020 18:14:50
User entered 'No (N)'	System	04 Sep 2020 18:14:50

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:14:43', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0f2ca00e-cd75-4ea7-b803-4ad2cc0dc8a7' User entered '04 Sep 2020 14:14'	System	04 Sep 2020 18:14:50
	System	04 Sep 2020 18:14:50

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 4'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:56:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f7784d5d-691c-42b5-bc7e-25fe02703fba' User entered 'Yes (Y)'	System	05 Sep 2020 16:57:15
	System	05 Sep 2020 16:57:15

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:56:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f7784d5d-691c-42b5-bc7e-25fe02703fba' User entered '98.2'	System	05 Sep 2020 16:57:15
	System	05 Sep 2020 16:57:15

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f7784d5d-691c-42b5-bc7e-25fe02703fba'	System	05 Sep 2020 16:57:15
User entered 'No (N)'	System	05 Sep 2020 16:57:15

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:12', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f7784d5d-691c-42b5-bc7e-25fe02703fba' User entered '05 Sep 2020 12:57'	System	05 Sep 2020 16:57:15
	System	05 Sep 2020 16:57:15

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 5'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '59d78eb9-6b55-4cfb-90de-97c8bfb88828' User entered 'Yes (Y)'	System	06 Sep 2020 18:24:42
	System	06 Sep 2020 18:24:42

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '59d78eb9-6b55-4cfb-90de-97c8bfb88828' User entered '97.0'	System	06 Sep 2020 18:24:42
	System	06 Sep 2020 18:24:42

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:33', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '59d78eb9-6b55-4cfb-90de-97c8bfb88828' User entered 'No (N)'	System	06 Sep 2020 18:24:42
	System	06 Sep 2020 18:24:42

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '59d78eb9-6b55-4cfb-90de-97c8bfb88828' User entered '06 Sep 2020 14:24'	System	06 Sep 2020 18:24:42
	System	06 Sep 2020 18:24:42

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 6'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:00:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '414b6ad7-1a47-447b-bf7f-a255e2ea7df3' User entered 'Yes (Y)'	System	07 Sep 2020 17:01:45
	System	07 Sep 2020 17:01:45

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:08', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '414b6ad7-1a47-447b-bf7f-a255e2ea7df3' User entered '97.0'	System	07 Sep 2020 17:01:45
	System	07 Sep 2020 17:01:45

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '414b6ad7-1a47-447b-bf7f-a255e2ea7df3'	System	07 Sep 2020 17:01:45
User entered 'No (N)'	System	07 Sep 2020 17:01:45

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '414b6ad7-1a47-447b-bf7f-a255e2ea7df3' User entered '07 Sep 2020 13:01'	System	07 Sep 2020 17:01:45
	System	07 Sep 2020 17:01:45

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 7'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:51:51', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1ecb2262-e66b-4a02-8dc6-e9b91081dff4' User entered 'Yes (Y)'	System	08 Sep 2020 17:52:14
	System	08 Sep 2020 17:52:14

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:51:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1ecb2262-e66b-4a02-8dc6-e9b91081dff4' User entered '97.3'	System	08 Sep 2020 17:52:14
	System	08 Sep 2020 17:52:14

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1ecb2262-e66b-4a02-8dc6-e9b91081dff4'	System	08 Sep 2020 17:52:14
User entered 'No (N)'	System	08 Sep 2020 17:52:14

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1ecb2262-e66b-4a02-8dc6-e9b91081dff4' User entered '08 Sep 2020 13:52'	System	08 Sep 2020 17:52:14
	System	08 Sep 2020 17:52:14

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:19:43', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9b998931-8728-4e9a-b7fa-1a56a5d81712'	System	02 Sep 2020 16:20:05
User entered 'None (1)'	System	02 Sep 2020 16:20:05

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:19:49', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9b998931-8728-4e9a-b7fa-1a56a5d81712'	System	02 Sep 2020 16:20:05
User entered 'No (N)'	System	02 Sep 2020 16:20:05

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:19:54', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9b998931-8728-4e9a-b7fa-1a56a5d81712' User entered 'No (N)'	System	02 Sep 2020 16:20:05
	System	02 Sep 2020 16:20:05

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:19:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9b998931-8728-4e9a-b7fa-1a56a5d81712'	System	02 Sep 2020 16:20:05
User entered 'None (1)'	System	02 Sep 2020 16:20:05

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:02', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9b998931-8728-4e9a-b7fa-1a56a5d81712' User entered '02 Sep 2020 12:20'	System	02 Sep 2020 16:20:05
	System	02 Sep 2020 16:20:05

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 14:32'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:32:01', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'de8fe703-c1f7-469c-8a1d-ace2d99f0315' User entered 'None (1)'	System	02 Sep 2020 21:33:39
	System	02 Sep 2020 21:33:39

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:32:06', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'de8fe703-c1f7-469c-8a1d-ace2d99f0315' User entered 'No (N)'	System	02 Sep 2020 21:33:39
	System	02 Sep 2020 21:33:39

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:32:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'de8fe703-c1f7-469c-8a1d-ace2d99f0315' User entered 'No (N)'	System	02 Sep 2020 21:33:39
	System	02 Sep 2020 21:33:39

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:33:22', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'de8fe703-c1f7-469c-8a1d-ace2d99f0315' User entered 'None (1)'	System	02 Sep 2020 21:33:39
	System	02 Sep 2020 21:33:39

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:33:36', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'de8fe703-c1f7-469c-8a1d-ace2d99f0315' User entered '02 Sep 2020 17:33'	System	02 Sep 2020 21:33:39
	System	02 Sep 2020 21:33:39

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 15:27'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 2'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:36', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '15c83fd9-d07c-42e4-97c5-e8a17df77b12' User entered 'None (1)'	System	03 Sep 2020 18:04:16
	System	03 Sep 2020 18:04:16

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '15c83fd9-d07c-42e4-97c5-e8a17df77b12' User entered 'No (N)'	System	03 Sep 2020 18:04:16
	System	03 Sep 2020 18:04:16

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:45', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '15c83fd9-d07c-42e4-97c5-e8a17df77b12' User entered 'No (N)'	System	03 Sep 2020 18:04:16
	System	03 Sep 2020 18:04:16

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:03:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '15c83fd9-d07c-42e4-97c5-e8a17df77b12' User entered 'None (1)'	System	03 Sep 2020 18:04:16
	System	03 Sep 2020 18:04:16

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '15c83fd9-d07c-42e4-97c5-e8a17df77b12' User entered '03 Sep 2020 14:04'	System	03 Sep 2020 18:04:16
	System	03 Sep 2020 18:04:16

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 3'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:06', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27396681-2ab5-4486-bf69-a36f77c8d26e' User entered 'None (1)'	System	04 Sep 2020 18:15:31
	System	04 Sep 2020 18:15:31

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27396681-2ab5-4486-bf69-a36f77c8d26e' User entered 'No (N)'	System	04 Sep 2020 18:15:31
	System	04 Sep 2020 18:15:31

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27396681-2ab5-4486-bf69-a36f77c8d26e' User entered 'No (N)'	System	04 Sep 2020 18:15:31
	System	04 Sep 2020 18:15:31

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27396681-2ab5-4486-bf69-a36f77c8d26e' User entered 'None (1)'	System	04 Sep 2020 18:15:31
	System	04 Sep 2020 18:15:31

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27396681-2ab5-4486-bf69-a36f77c8d26e' User entered '04 Sep 2020 14:15'	System	04 Sep 2020 18:15:31
	System	04 Sep 2020 18:15:31

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 4'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f9f97237-2c53-4158-8fcd-4184dd9a91e4' User entered 'None (1)'	System	05 Sep 2020 16:57:45
	System	05 Sep 2020 16:57:45

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f9f97237-2c53-4158-8fcd-4184dd9a91e4' User entered 'No (N)'	System	05 Sep 2020 16:57:45
	System	05 Sep 2020 16:57:45

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f9f97237-2c53-4158-8fcd-4184dd9a91e4' User entered 'No (N)'	System	05 Sep 2020 16:57:45
	System	05 Sep 2020 16:57:45

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f9f97237-2c53-4158-8fcd-4184dd9a91e4' User entered 'None (1)'	System	05 Sep 2020 16:57:45
	System	05 Sep 2020 16:57:45

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:43', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f9f97237-2c53-4158-8fcd-4184dd9a91e4' User entered '05 Sep 2020 12:57'	System	05 Sep 2020 16:57:45
	System	05 Sep 2020 16:57:45

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 5'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c4928400-4ece-4690-8324-a2a5a31482bd' User entered 'None (1)'	System	06 Sep 2020 18:25:09
	System	06 Sep 2020 18:25:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:51', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c4928400-4ece-4690-8324-a2a5a31482bd' User entered 'No (N)'	System	06 Sep 2020 18:25:09
	System	06 Sep 2020 18:25:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:55', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c4928400-4ece-4690-8324-a2a5a31482bd' User entered 'No (N)'	System	06 Sep 2020 18:25:09
	System	06 Sep 2020 18:25:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:24:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c4928400-4ece-4690-8324-a2a5a31482bd' User entered 'None (1)'	System	06 Sep 2020 18:25:09
	System	06 Sep 2020 18:25:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c4928400-4ece-4690-8324-a2a5a31482bd' User entered '06 Sep 2020 14:25'	System	06 Sep 2020 18:25:09
	System	06 Sep 2020 18:25:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 6'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:26', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22b7cb45-29d2-49d6-9019-555bd3caf8d2'	System	07 Sep 2020 17:02:09
User entered 'None (1)'	System	07 Sep 2020 17:02:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22b7cb45-29d2-49d6-9019-555bd3caf8d2' User entered 'No (N)'	System	07 Sep 2020 17:02:09
	System	07 Sep 2020 17:02:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:34', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22b7cb45-29d2-49d6-9019-555bd3caf8d2' User entered 'No (N)'	System	07 Sep 2020 17:02:09
	System	07 Sep 2020 17:02:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22b7cb45-29d2-49d6-9019-555bd3caf8d2'	System	07 Sep 2020 17:02:09
User entered 'None (1)'	System	07 Sep 2020 17:02:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22b7cb45-29d2-49d6-9019-555bd3caf8d2' User entered '07 Sep 2020 13:01'	System	07 Sep 2020 17:02:09
	System	07 Sep 2020 17:02:09

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 7'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:17', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2c2cba71-c84f-4a02-9880-46e6dac2403b' User entered 'None (1)'	System	08 Sep 2020 17:52:47
	System	08 Sep 2020 17:52:47

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:20', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2c2cba71-c84f-4a02-9880-46e6dac2403b' User entered 'No (N)'	System	08 Sep 2020 17:52:47
	System	08 Sep 2020 17:52:47

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2c2cba71-c84f-4a02-9880-46e6dac2403b' User entered 'No (N)'	System	08 Sep 2020 17:52:47
	System	08 Sep 2020 17:52:47

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:34', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2c2cba71-c84f-4a02-9880-46e6dac2403b' User entered 'None (1)'	System	08 Sep 2020 17:52:47
	System	08 Sep 2020 17:52:47

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:44', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2c2cba71-c84f-4a02-9880-46e6dac2403b' User entered '08 Sep 2020 13:52'	System	08 Sep 2020 17:52:47
	System	08 Sep 2020 17:52:47

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:35', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'None (0)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:41', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered 'No (N)'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T12:20:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a8f188bc-9c33-45fa-90ef-c6ce4341a3e1' User entered '02 Sep 2020 12:20'	System	02 Sep 2020 16:20:54
	System	02 Sep 2020 16:20:54

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 12:02'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 14:32'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:33:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:33:55', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'None (0)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered 'No (N)'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-02T17:34:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6aed33cb-d2c7-41fe-ae41-7580e2d0f914' User entered '02 Sep 2020 17:34'	System	02 Sep 2020 21:34:37
	System	02 Sep 2020 21:34:37

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Sep 2020 15:27'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 2'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:26', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:42', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'None (0)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:04:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered 'No (N)'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-03T14:05:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '9a45b0ce-c0de-48a6-accf-dae303c09b3e' User entered '03 Sep 2020 14:05'	System	03 Sep 2020 18:05:07
	System	03 Sep 2020 18:05:07

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 3'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:39', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:15:51', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:16:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:16:08', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:16:12', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'None (0)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:16:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered 'No (N)'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-04T14:16:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fdaf9ac7-3379-4413-acd6-81fa8acb5272' User entered '04 Sep 2020 14:16'	System	04 Sep 2020 18:16:34
	System	04 Sep 2020 18:16:34

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 4'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:57:56', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:08', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:12', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'None (0)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered 'No (N)'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-05T12:58:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1371b257-bf3a-4be4-9e4c-d97845c96b7f' User entered '05 Sep 2020 12:58'	System	05 Sep 2020 16:58:30
	System	05 Sep 2020 16:58:30

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 5'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:22', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:36', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'None (0)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered 'No (N)'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-06T14:25:54', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e55d3f7d-bd22-4476-b80f-0cf898f5f88c' User entered '06 Sep 2020 14:25'	System	06 Sep 2020 18:25:55
	System	06 Sep 2020 18:25:55

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 6'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:01:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:03', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'None (0)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered 'No (N)'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-07T13:02:33', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c3a5f394-b2bd-44d5-9434-25f7b95d4b52' User entered '07 Sep 2020 13:02'	System	07 Sep 2020 17:02:38
	System	07 Sep 2020 17:02:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 7'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:56', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:52:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:53:02', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:53:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'None (0)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:53:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered 'No (N)'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE207F00-7115-44BA-94EF-4DD234E54673)', Time: '2020-09-08T13:53:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '00599171-8d99-4f49-8c13-8ab8e7471bcb' User entered '08 Sep 2020 13:53'	System	08 Sep 2020 17:53:27
	System	08 Sep 2020 17:53:27

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:16:38

US3512193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:18:52

US3512193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:46:24
User entered '9 Sep 2020'	Sheldon Warren (b) (4)	16 Sep 2020 19:18:52

US3512193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:18:52

US3512193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:18:52

US3512193

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:18:58

US3512193

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	16 Sep 2020 19:18:58

US3512193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:19:13

US3512193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	16 Sep 2020 19:19:25
answered by data change (Site from System).		
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	16 Sep 2020 19:19:25
User entered '16 Sep 2020' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	16 Sep 2020 19:19:25
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	16 Sep 2020 19:19:13
User entered '15 Sep 2020'	Sheldon Warren (b) (4)	16 Sep 2020 19:19:13
	(b) (4)	

US3512193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:19:13

US3512193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:19:13

US3512193

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	16 Sep 2020 19:19:31

US3512193

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	16 Sep 2020 19:19:31

US3512193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 21:38:35

US3512193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Sep 2020'	Taylor Johnson (b) (4)	23 Sep 2020 21:38:35

US3512193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 21:38:35

US3512193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 21:38:35

US3512193

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 21:38:52

US3512193

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	23 Sep 2020 21:38:52

US3512193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:24

US3512193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Oct 2020'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:24

US3512193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	02 Oct 2020 15:24:24

US3512193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'VISIT2'	System	02 Oct 2020 15:24:24

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Oct 2020'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:24'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Oct 2020 10:24'	System	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '97.1' F	Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '66'	Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'bpm'	System	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '16'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'breaths/min'	System	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '140'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '82'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Oct 2020 15:24:58

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Oct 2020'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '11:33'	Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Oct 2020 11:33'	System	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98.0' F	Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '69'	Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'bpm'	System	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '16'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'breaths/min'	System	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '122'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '76'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	02 Oct 2020 15:38:35

US3512193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:25:03

US3512193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:25:03

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '2 Oct 2020'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '11:02'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Oct 2020 11:02'	System	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Right Arm (RIGHT ARM)'	Allison Crain (b) (4)	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'ONCE'	System	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 15:27:13

US3512193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Oct 2020 15:25:18

US3512193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4)	08 Nov 2020 12:51:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Do to lack of supplies at site, unscheduled kit was used for this scheduled visit with monitor approval for all.' (Site from DM).	Allison Crain (b) (4)	23 Oct 2020 15:59:49
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:21:59
User entered '2 Oct 2020'	Allison Crain (b) (4)	02 Oct 2020 15:25:18

US3512193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '10:44' reason for change: Data Entry Error	System	02 Oct 2020 17:10:45
User opened query 'Data is required. Please provide.' (Site from System).	Allison Crain (b) (4)	02 Oct 2020 17:10:45
User entered empty.	(b) (4)	
	System	02 Oct 2020 15:25:18
	Allison Crain (b) (4)	02 Oct 2020 15:25:18
	(b) (4)	

US3512193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Oct 2020 10:44'	System	02 Oct 2020 17:10:45
User entered empty.	System	02 Oct 2020 15:25:18

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:42:16
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Due to lack of supplies on site, UNSCHEDULED lab kits were used for the Visit 2 Day 29 labs. This was approved by monitor and are not two separate visits.' (Site from DM).	Allison Crain (b) (4) (b) (4)	21 Oct 2020 12:36:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:44:43
User entered '2 Oct 2020'	Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:34'	Allison Crain (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '2 Oct 2020 10:34'	System	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered empty.	System	02 Oct 2020 15:25:30

US3512193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Oct 2020 15:25:37

US3512193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	02 Oct 2020 15:25:37

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:33:57', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '838a2d22-d39f-41ed-a551-8fea6e2425b9' User entered 'Yes (Y)'	System	02 Oct 2020 15:34:29
	System	02 Oct 2020 15:34:29

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:34:12', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '838a2d22-d39f-41ed-a551-8fea6e2425b9' User entered '98.0'	System	02 Oct 2020 15:34:29
	System	02 Oct 2020 15:34:29

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:34:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '838a2d22-d39f-41ed-a551-8fea6e2425b9'	System	02 Oct 2020 15:34:29
User entered 'No (N)'	System	02 Oct 2020 15:34:29

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:34:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '838a2d22-d39f-41ed-a551-8fea6e2425b9' User entered '02 Oct 2020 11:34'	System	02 Oct 2020 15:34:29
	System	02 Oct 2020 15:34:29

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 11:22'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 13:52'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:07:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e699ce52-922d-4a3c-be96-57de64b50b17' User entered 'Yes (Y)'	System	02 Oct 2020 21:08:08
	System	02 Oct 2020 21:08:08

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:07:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e699ce52-922d-4a3c-be96-57de64b50b17' User entered '97.0'	System	02 Oct 2020 21:08:08
	System	02 Oct 2020 21:08:08

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:07:55', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e699ce52-922d-4a3c-be96-57de64b50b17' User entered 'No (N)'	System	02 Oct 2020 21:08:08
	System	02 Oct 2020 21:08:08

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e699ce52-922d-4a3c-be96-57de64b50b17' User entered '02 Oct 2020 17:08'	System	02 Oct 2020 21:08:08
	System	02 Oct 2020 21:08:08

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 14:47'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 2'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'ee2126e4-f4cc-48f7-aa38-5c0dfa722c2f' User entered 'Yes (Y)'	System	03 Oct 2020 16:50:47
	System	03 Oct 2020 16:50:47

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'ee2126e4-f4cc-48f7-aa38-5c0dfa722c2f' User entered '97.1'	System	03 Oct 2020 16:50:47
	System	03 Oct 2020 16:50:47

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'ee2126e4-f4cc-48f7-aa38-5c0dfa722c2f' User entered 'No (N)'	System	03 Oct 2020 16:50:47
	System	03 Oct 2020 16:50:47

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:45', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'ee2126e4-f4cc-48f7-aa38-5c0dfa722c2f' User entered '03 Oct 2020 12:50'	System	03 Oct 2020 16:50:47
	System	03 Oct 2020 16:50:47

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 3'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '5085fe6c-d556-4531-9b53-61e2e2913239' User entered 'Yes (Y)'	System	05 Oct 2020 13:28:40
	System	05 Oct 2020 13:28:40

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:29', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '5085fe6c-d556-4531-9b53-61e2e2913239' User entered '97.2'	System	05 Oct 2020 13:28:40
	System	05 Oct 2020 13:28:40

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:33', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '5085fe6c-d556-4531-9b53-61e2e2913239' User entered 'No (N)'	System	05 Oct 2020 13:28:40
	System	05 Oct 2020 13:28:40

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '5085fe6c-d556-4531-9b53-61e2e2913239' User entered '05 Oct 2020 09:28'	System	05 Oct 2020 13:28:40
	System	05 Oct 2020 13:28:40

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 4'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:07:44', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6156c950-7066-4ee1-a0bf-9dc47b6edd02' User entered 'Yes (Y)'	System	05 Oct 2020 16:08:12
	System	05 Oct 2020 16:08:12

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:07:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6156c950-7066-4ee1-a0bf-9dc47b6edd02' User entered '97.2'	System	05 Oct 2020 16:08:12
	System	05 Oct 2020 16:08:12

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:07:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6156c950-7066-4ee1-a0bf-9dc47b6edd02'	System	05 Oct 2020 16:08:12
User entered 'No (N)'	System	05 Oct 2020 16:08:12

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6156c950-7066-4ee1-a0bf-9dc47b6edd02' User entered '05 Oct 2020 12:08'	System	05 Oct 2020 16:08:12
	System	05 Oct 2020 16:08:12

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 5'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:46:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8a07d9c2-07e5-4d04-b526-1973eaec890b' User entered 'Yes (Y)'	System	06 Oct 2020 16:47:24
	System	06 Oct 2020 16:47:24

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:06', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8a07d9c2-07e5-4d04-b526-1973eaec890b' User entered '97.4'	System	06 Oct 2020 16:47:24
	System	06 Oct 2020 16:47:24

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8a07d9c2-07e5-4d04-b526-1973eaec890b' User entered 'No (N)'	System	06 Oct 2020 16:47:24
	System	06 Oct 2020 16:47:24

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:17', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8a07d9c2-07e5-4d04-b526-1973eaec890b' User entered '06 Oct 2020 12:47'	System	06 Oct 2020 16:47:24
	System	06 Oct 2020 16:47:24

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 6'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:01:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1dbd3ee-ff2f-4f9d-a8a7-d37be839429b' User entered 'Yes (Y)'	System	07 Oct 2020 21:02:15
	System	07 Oct 2020 21:02:15

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:01:56', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1dbd3ee-ff2f-4f9d-a8a7-d37be839429b' User entered '97.2'	System	07 Oct 2020 21:02:15
	System	07 Oct 2020 21:02:15

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1dbd3ee-ff2f-4f9d-a8a7-d37be839429b'	System	07 Oct 2020 21:02:15
User entered 'No (N)'	System	07 Oct 2020 21:02:15

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:13', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1dbd3ee-ff2f-4f9d-a8a7-d37be839429b' User entered '07 Oct 2020 17:02'	System	07 Oct 2020 21:02:15
	System	07 Oct 2020 21:02:15

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 7'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '34b7caac-bafb-4e5b-9165-b748372a4d2a' User entered 'Yes (Y)'	System	08 Oct 2020 18:12:32
	System	08 Oct 2020 18:12:32

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '34b7caac-bafb-4e5b-9165-b748372a4d2a' User entered '97.7'	System	08 Oct 2020 18:12:32
	System	08 Oct 2020 18:12:32

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '34b7caac-bafb-4e5b-9165-b748372a4d2a' User entered 'No (N)'	System	08 Oct 2020 18:12:32
	System	08 Oct 2020 18:12:32

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '34b7caac-bafb-4e5b-9165-b748372a4d2a' User entered '08 Oct 2020 14:12'	System	08 Oct 2020 18:12:32
	System	08 Oct 2020 18:12:32

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:34:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0af4f23c-9542-45b5-8726-da9d3c72ea97'	System	02 Oct 2020 15:36:14
User entered 'None (1)'	System	02 Oct 2020 15:36:14

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:35:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0af4f23c-9542-45b5-8726-da9d3c72ea97'	System	02 Oct 2020 15:36:14
User entered 'No (N)'	System	02 Oct 2020 15:36:14

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:35:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0af4f23c-9542-45b5-8726-da9d3c72ea97' User entered 'No (N)'	System	02 Oct 2020 15:36:14
	System	02 Oct 2020 15:36:14

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:01', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0af4f23c-9542-45b5-8726-da9d3c72ea97'	System	02 Oct 2020 15:36:14
User entered 'None (1)'	System	02 Oct 2020 15:36:14

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0af4f23c-9542-45b5-8726-da9d3c72ea97'	System	02 Oct 2020 15:36:14
User entered '02 Oct 2020 11:36'	System	02 Oct 2020 15:36:14

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 11:22'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 13:52'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fad7d284-40d4-4113-a6bd-c2406b21b1eb' User entered 'None (1)'	System	02 Oct 2020 21:08:50
	System	02 Oct 2020 21:08:50

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fad7d284-40d4-4113-a6bd-c2406b21b1eb' User entered 'No (N)'	System	02 Oct 2020 21:08:50
	System	02 Oct 2020 21:08:50

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fad7d284-40d4-4113-a6bd-c2406b21b1eb' User entered 'No (N)'	System	02 Oct 2020 21:08:50
	System	02 Oct 2020 21:08:50

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fad7d284-40d4-4113-a6bd-c2406b21b1eb' User entered 'None (1)'	System	02 Oct 2020 21:08:50
	System	02 Oct 2020 21:08:50

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'fad7d284-40d4-4113-a6bd-c2406b21b1eb' User entered '02 Oct 2020 17:08'	System	02 Oct 2020 21:08:50
	System	02 Oct 2020 21:08:50

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 14:47'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 2'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bb9c5df7-40c9-4532-ace6-60f8cb9bc53c'	System	03 Oct 2020 16:51:20
User entered 'None (1)'	System	03 Oct 2020 16:51:20

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:50:56', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bb9c5df7-40c9-4532-ace6-60f8cb9bc53c' User entered 'No (N)'	System	03 Oct 2020 16:51:20
	System	03 Oct 2020 16:51:20

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bb9c5df7-40c9-4532-ace6-60f8cb9bc53c' User entered 'No (N)'	System	03 Oct 2020 16:51:20
	System	03 Oct 2020 16:51:20

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bb9c5df7-40c9-4532-ace6-60f8cb9bc53c'	System	03 Oct 2020 16:51:20
User entered 'None (1)'	System	03 Oct 2020 16:51:20

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bb9c5df7-40c9-4532-ace6-60f8cb9bc53c' User entered '03 Oct 2020 12:51'	System	03 Oct 2020 16:51:20
	System	03 Oct 2020 16:51:20

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 3'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:44', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6c8dcee7-5fb8-4ea9-95c6-d5edb4d9ee64'	System	05 Oct 2020 13:29:07
User entered 'None (1)'	System	05 Oct 2020 13:29:07

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6c8dcee7-5fb8-4ea9-95c6-d5edb4d9ee64' User entered 'No (N)'	System	05 Oct 2020 13:29:07
	System	05 Oct 2020 13:29:07

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6c8dcee7-5fb8-4ea9-95c6-d5edb4d9ee64' User entered 'No (N)'	System	05 Oct 2020 13:29:07
	System	05 Oct 2020 13:29:07

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:28:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6c8dcee7-5fb8-4ea9-95c6-d5edb4d9ee64' User entered 'None (1)'	System	05 Oct 2020 13:29:07
	System	05 Oct 2020 13:29:07

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6c8dcee7-5fb8-4ea9-95c6-d5edb4d9ee64' User entered '05 Oct 2020 09:29'	System	05 Oct 2020 13:29:07
	System	05 Oct 2020 13:29:07

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 4'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '92466276-78eb-4353-bf82-d0ea1fd96d25'	System	05 Oct 2020 16:08:51
User entered 'None (1)'	System	05 Oct 2020 16:08:51

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '92466276-78eb-4353-bf82-d0ea1fd96d25' User entered 'No (N)'	System	05 Oct 2020 16:08:51
	System	05 Oct 2020 16:08:51

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '92466276-78eb-4353-bf82-d0ea1fd96d25' User entered 'No (N)'	System	05 Oct 2020 16:08:51
	System	05 Oct 2020 16:08:51

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '92466276-78eb-4353-bf82-d0ea1fd96d25' User entered 'None (1)'	System	05 Oct 2020 16:08:51
	System	05 Oct 2020 16:08:51

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '92466276-78eb-4353-bf82-d0ea1fd96d25' User entered '05 Oct 2020 12:08'	System	05 Oct 2020 16:08:51
	System	05 Oct 2020 16:08:51

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 5'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2468303-103c-4902-9ff2-b64b1dc968fd' User entered 'None (1)'	System	06 Oct 2020 16:47:47
	System	06 Oct 2020 16:47:47

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2468303-103c-4902-9ff2-b64b1dc968fd' User entered 'No (N)'	System	06 Oct 2020 16:47:47
	System	06 Oct 2020 16:47:47

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2468303-103c-4902-9ff2-b64b1dc968fd' User entered 'No (N)'	System	06 Oct 2020 16:47:47
	System	06 Oct 2020 16:47:47

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:37', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2468303-103c-4902-9ff2-b64b1dc968fd' User entered 'None (1)'	System	06 Oct 2020 16:47:47
	System	06 Oct 2020 16:47:47

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2468303-103c-4902-9ff2-b64b1dc968fd' User entered '06 Oct 2020 12:47'	System	06 Oct 2020 16:47:47
	System	06 Oct 2020 16:47:47

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 6'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '032cc9a6-20cf-4b66-ae2e-ebf1c70c1f88'	System	07 Oct 2020 21:02:46
User entered 'None (1)'	System	07 Oct 2020 21:02:46

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '032cc9a6-20cf-4b66-ae2e-ebf1c70c1f88'	System	07 Oct 2020 21:02:46
User entered 'No (N)'	System	07 Oct 2020 21:02:46

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '032cc9a6-20cf-4b66-ae2e-ebf1c70c1f88'	System	07 Oct 2020 21:02:46
User entered 'No (N)'	System	07 Oct 2020 21:02:46

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '032cc9a6-20cf-4b66-ae2e-ebf1c70c1f88'	System	07 Oct 2020 21:02:46
User entered 'None (1)'	System	07 Oct 2020 21:02:46

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:02:43', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '032cc9a6-20cf-4b66-ae2e-ebf1c70c1f88' User entered '07 Oct 2020 17:02'	System	07 Oct 2020 21:02:46
	System	07 Oct 2020 21:02:46

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 7'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:33', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e6606bad-a2d2-40fc-98c6-4b5471295ae3'	System	08 Oct 2020 18:12:56
User entered 'None (1)'	System	08 Oct 2020 18:12:56

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:37', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e6606bad-a2d2-40fc-98c6-4b5471295ae3' User entered 'No (N)'	System	08 Oct 2020 18:12:56
	System	08 Oct 2020 18:12:56

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e6606bad-a2d2-40fc-98c6-4b5471295ae3' User entered 'No (N)'	System	08 Oct 2020 18:12:56
	System	08 Oct 2020 18:12:56

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e6606bad-a2d2-40fc-98c6-4b5471295ae3' User entered 'None (1)'	System	08 Oct 2020 18:12:56
	System	08 Oct 2020 18:12:56

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:12:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e6606bad-a2d2-40fc-98c6-4b5471295ae3'	System	08 Oct 2020 18:12:56
User entered '08 Oct 2020 14:12'	System	08 Oct 2020 18:12:56

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:35', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:39', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'None (0)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:36:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered 'No (N)'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T11:37:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '08de4366-074f-4c50-b229-ae33cb2ecd1a' User entered '02 Oct 2020 11:37'	System	02 Oct 2020 15:37:03
	System	02 Oct 2020 15:37:03

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 11:22'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 13:52'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:08:57', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'None (0)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered 'No (N)'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-02T17:09:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '0618ce53-9e01-4761-a891-310e18cd5b99' User entered '02 Oct 2020 17:09'	System	02 Oct 2020 21:09:29
	System	02 Oct 2020 21:09:29

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '02 Oct 2020 14:47'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 2'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:22', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'None (0)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:44', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'No interference with activity (1)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'None (0)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:51:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'None (0)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:52:03', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'None (0)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:52:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'None (0)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:52:13', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered 'No (N)'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-03T12:52:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f34016b7-9f27-49c9-ada8-e3ac00a360ff' User entered '03 Oct 2020 12:52'	System	03 Oct 2020 16:52:28
	System	03 Oct 2020 16:52:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 3'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:19', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'None (0)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:35', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered 'No (N)'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T09:29:48', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4c466d65-f4ff-4c47-86a4-050101ef18d5' User entered '05 Oct 2020 09:29'	System	05 Oct 2020 13:29:50
	System	05 Oct 2020 13:29:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 4'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:08:54', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:01', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:09', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:13', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:16', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'None (0)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:20', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered 'No (N)'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-05T12:09:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '16260ab0-015f-40d7-b3d7-4d3b6ace6de2' User entered '05 Oct 2020 12:09'	System	05 Oct 2020 16:09:35
	System	05 Oct 2020 16:09:35

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 5'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:47:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:02', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:10', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:13', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'None (0)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered 'No (N)'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-06T12:48:26', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '35ac4a5a-a27f-440e-8796-28dd851611ae' User entered '06 Oct 2020 12:48'	System	06 Oct 2020 16:48:28
	System	06 Oct 2020 16:48:28

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 6'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:08', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:20', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'None (0)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:39', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered 'No (N)'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-07T17:44:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '426b12ce-7365-4e66-a853-4222f5245099' User entered '07 Oct 2020 17:44'	System	07 Oct 2020 21:44:50
	System	07 Oct 2020 21:44:50

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Oct 2020 15:27:13
User entered 'Day 7'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:11', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:14', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'None (0)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:22', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered 'No (N)'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-10-08T14:13:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a4abd52d-c0fc-4a7d-ae63-e5206c3bec29' User entered '08 Oct 2020 14:13'	System	08 Oct 2020 18:13:33
	System	08 Oct 2020 18:13:33

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:27:13

US3512193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:27:13

US3512193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Oct 2020 20:55:16

US3512193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '12 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	12 Oct 2020 20:55:16

US3512193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	12 Oct 2020 20:55:16

US3512193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Oct 2020 20:55:16

US3512193

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Oct 2020 20:55:22

US3512193

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	12 Oct 2020 20:55:22

US3512193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	19 Oct 2020 19:25:59

US3512193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '19 Oct 2020'	Sheldon Warren (b) (4)	19 Oct 2020 19:25:59

US3512193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	19 Oct 2020 19:25:59

US3512193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	19 Oct 2020 19:25:59

US3512193

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	19 Oct 2020 19:26:04

US3512193

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	19 Oct 2020 19:26:04

US3512193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Oct 2020 19:58:52

US3512193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '26 Oct 2020'	Sheldon Warren (b) (4)	26 Oct 2020 19:58:52

US3512193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	26 Oct 2020 19:58:52

US3512193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	26 Oct 2020 19:58:52

US3512193

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Oct 2020 19:58:56

US3512193

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	26 Oct 2020 19:58:56

US3512193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:41:57

US3512193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:22:19
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit was completed out of window due to subjects illness visits and hospitalization for atrial fibrillation. Data confirmed as is.' (Site from System).	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 21:43:07
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	21 Nov 2020 21:41:57
User entered '17 Nov 2020'	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 21:41:57

US3512193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:41:57

US3512193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'VISIT3'	System	21 Nov 2020 21:41:57

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '17 Nov 2020'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '11:45'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '17 Nov 2020 11:45'	System	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '97.8' F	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Oral (Oral)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '86'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'bpm'	System	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '12'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'breaths/min'	System	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '101'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '72'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'mmHg'	System	21 Nov 2020 21:44:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29

US3512193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:37

US3512193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:37

US3512193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:55

US3512193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '17 Nov 2020'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:55

US3512193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '12:12'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:44:55

US3512193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered '17 Nov 2020 12:12'	System	21 Nov 2020 21:44:55

US3512193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	21 Nov 2020 21:45:02

US3512193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	21 Nov 2020 21:45:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 64'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:03:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'Yes (Y)'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:03:39', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'No (N)'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:03:53', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'Yes (Y)'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '1'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:25', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '0'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:33', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:42', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'Yes (Y)'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:50', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-03T13:04:59', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4cc8b5b7-4b10-4cb5-9eac-c902bd917ccf' User entered '03 Nov 2020 13:04:59'	System	03 Nov 2020 18:05:10
	System	03 Nov 2020 18:05:10

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 71'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:17:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a' User entered 'Yes (Y)'	System	09 Nov 2020 18:19:02
	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:17:45', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a' User entered 'No (N)'	System	09 Nov 2020 18:19:02
	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:18:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a' User entered 'No (N)'	System	09 Nov 2020 18:19:02
	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:18:16', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a' User entered 'Yes (Y)'	System	09 Nov 2020 18:19:02
	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:18:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a'	System	09 Nov 2020 18:19:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-09T13:18:40', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'f915cc21-df57-4c3c-9550-ea87a94a6e8a' User entered '09 Nov 2020 13:18:40'	System	09 Nov 2020 18:19:02
	System	09 Nov 2020 18:19:02

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered 'Day 78'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T11:59:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46'	System	17 Nov 2020 17:00:21
User entered 'Yes (Y)'	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T11:59:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46'	System	17 Nov 2020 17:00:21
User entered 'No (N)'	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T11:59:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46'	System	17 Nov 2020 17:00:21
User entered 'No (N)'	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T11:59:45', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46'	System	17 Nov 2020 17:00:21
User entered 'Yes (Y)'	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T11:59:57', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46'	System	17 Nov 2020 17:00:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-17T12:00:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '8aa3b205-fea0-43a8-a48a-b82aba092f46' User entered '17 Nov 2020 12:00:05'	System	17 Nov 2020 17:00:21
	System	17 Nov 2020 17:00:21

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 16:16:38

US3512193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:28
Data entry locked.	System	02 Sep 2020 16:16:38
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 16:16:38

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422' User entered 'Yes (Y)'	System	24 Nov 2020 17:03:07
	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422'	System	24 Nov 2020 17:03:07
User entered 'No (N)'	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:36', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422'	System	24 Nov 2020 17:03:07
User entered 'No (N)'	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:46', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422'	System	24 Nov 2020 17:03:07
User entered 'Yes (Y)'	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422'	System	24 Nov 2020 17:03:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-24T12:02:57', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '4fba1278-f240-4b31-8970-6ae816ca8422' User entered '24 Nov 2020 12:02:57'	System	24 Nov 2020 17:03:07

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-28T08:26:51', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '881436a8-dd28-45ca-a97c-a1d0bf6fc400'	System	28 Nov 2020 13:27:06
User entered 'No (N)'	System	28 Nov 2020 13:27:06

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-28T08:26:56', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '881436a8-dd28-45ca-a97c-a1d0bf6fc400'	System	28 Nov 2020 13:27:06
User entered 'No (N)'	System	28 Nov 2020 13:27:06

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-11-28T08:27:04', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '881436a8-dd28-45ca-a97c-a1d0bf6fc400'	System	28 Nov 2020 13:27:06
User entered '28 Nov 2020 08:27:04'	System	28 Nov 2020 13:27:06

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-04T08:52:26', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'adce6466-426f-4504-86ed-e92a24b2cd88' User entered 'No (N)'	System	04 Dec 2020 13:52:55
	System	04 Dec 2020 13:52:55

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-04T08:52:34', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'adce6466-426f-4504-86ed-e92a24b2cd88'	System	04 Dec 2020 13:52:55
User entered 'No (N)'	System	04 Dec 2020 13:52:55

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-04T08:52:52', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'adce6466-426f-4504-86ed-e92a24b2cd88' User entered '04 Dec 2020 08:52:52'	System	04 Dec 2020 13:52:55
	System	04 Dec 2020 13:52:55

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-11T16:01:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1d83262-714c-48c2-a0c5-78fb718dc560'	System	11 Dec 2020 21:01:27
User entered 'No (N)'	System	11 Dec 2020 21:01:27

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-11T16:01:09', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1d83262-714c-48c2-a0c5-78fb718dc560'	System	11 Dec 2020 21:01:27
User entered 'No (N)'	System	11 Dec 2020 21:01:27

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-11T16:01:23', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c1d83262-714c-48c2-a0c5-78fb718dc560' User entered '11 Dec 2020 16:01:23'	System	11 Dec 2020 21:01:27
	System	11 Dec 2020 21:01:27

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-19T10:55:18', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '86740375-aed5-48db-8409-d1a990fc26ff' User entered 'No (N)'	System	19 Dec 2020 15:55:33

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-19T10:55:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '86740375-aed5-48db-8409-d1a990fc26ff' User entered 'No (N)'	System	19 Dec 2020 15:55:33

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-19T10:55:29', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '86740375-aed5-48db-8409-d1a990fc26ff' User entered '19 Dec 2020 10:55:29'	System	19 Dec 2020 15:55:33
	System	19 Dec 2020 15:55:33

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-26T17:01:15', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'dabf70b1-d96d-4d8f-9b10-7edc8462abb5' User entered 'No (N)'	System	26 Dec 2020 22:01:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-26T17:01:21', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'dabf70b1-d96d-4d8f-9b10-7edc8462abb5' User entered 'No (N)'	System	26 Dec 2020 22:01:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2020-12-26T17:01:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'dabf70b1-d96d-4d8f-9b10-7edc8462abb5' User entered '26 Dec 2020 17:01:28'	System	26 Dec 2020 22:01:31
	System	26 Dec 2020 22:01:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-01T12:13:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a9354ab2-e5aa-401c-bf8b-d58619b2cd00'	System	01 Jan 2021 17:13:39
User entered 'No (N)'	System	01 Jan 2021 17:13:39

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-01T12:13:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a9354ab2-e5aa-401c-bf8b-d58619b2cd00'	System	01 Jan 2021 17:13:39
User entered 'No (N)'	System	01 Jan 2021 17:13:39

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-01T12:13:36', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'a9354ab2-e5aa-401c-bf8b-d58619b2cd00' User entered '01 Jan 2021 12:13:36'	System	01 Jan 2021 17:13:39
	System	01 Jan 2021 17:13:39

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-08T12:54:28', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2683bc4-d305-4be0-9691-e457f0a6dbd3' User entered 'No (N)'	System	08 Jan 2021 17:54:48
	System	08 Jan 2021 17:54:48

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-08T12:54:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2683bc4-d305-4be0-9691-e457f0a6dbd3' User entered 'No (N)'	System	08 Jan 2021 17:54:48
	System	08 Jan 2021 17:54:48

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-08T12:54:44', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'c2683bc4-d305-4be0-9691-e457f0a6dbd3' User entered '08 Jan 2021 12:54:44'	System	08 Jan 2021 17:54:48
	System	08 Jan 2021 17:54:48

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-15T10:01:07', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'cb98f869-0295-4257-b5b3-c02304a6b65c' User entered 'No (N)'	System	15 Jan 2021 15:02:01
	System	15 Jan 2021 15:02:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-15T10:01:30', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'cb98f869-0295-4257-b5b3-c02304a6b65c'	System	15 Jan 2021 15:02:01
User entered 'No (N)'	System	15 Jan 2021 15:02:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-15T10:01:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'cb98f869-0295-4257-b5b3-c02304a6b65c' User entered '15 Jan 2021 10:01:58'	System	15 Jan 2021 15:02:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-22T09:02:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22a938ac-bbe3-4f2c-8d67-e423053b3bee' User entered 'No (N)'	System	22 Jan 2021 14:03:30
	System	22 Jan 2021 14:03:30

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-22T09:03:08', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22a938ac-bbe3-4f2c-8d67-e423053b3bee' User entered 'No (N)'	System	22 Jan 2021 14:03:30

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-22T09:03:13', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '22a938ac-bbe3-4f2c-8d67-e423053b3bee' User entered '22 Jan 2021 09:03:13'	System	22 Jan 2021 14:03:30
	System	22 Jan 2021 14:03:30

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-29T09:55:27', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e3b3141d-ba30-4fd6-8397-3959c14d61d5'	System	29 Jan 2021 14:55:41
User entered 'No (N)'	System	29 Jan 2021 14:55:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-29T09:55:32', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e3b3141d-ba30-4fd6-8397-3959c14d61d5'	System	29 Jan 2021 14:55:41
User entered 'No (N)'	System	29 Jan 2021 14:55:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-01-29T09:55:38', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'e3b3141d-ba30-4fd6-8397-3959c14d61d5' User entered '29 Jan 2021 09:55:38'	System	29 Jan 2021 14:55:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-05T11:54:24', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '550ff7fe-c3d8-407d-bc59-a3d6d94cc8f2' User entered 'No (N)'	System	05 Feb 2021 16:54:41
	System	05 Feb 2021 16:54:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-05T11:54:34', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '550ff7fe-c3d8-407d-bc59-a3d6d94cc8f2' User entered 'No (N)'	System	05 Feb 2021 16:54:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-05T11:54:39', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '550ff7fe-c3d8-407d-bc59-a3d6d94cc8f2' User entered '05 Feb 2021 11:54:39'	System	05 Feb 2021 16:54:41
	System	05 Feb 2021 16:54:41

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-14T12:06:58', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'be494948-8610-4913-a509-55af78458dfd' User entered 'No (N)'	System	14 Feb 2021 17:12:01
	System	14 Feb 2021 17:12:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-14T12:07:01', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'be494948-8610-4913-a509-55af78458dfd' User entered 'No (N)'	System	14 Feb 2021 17:12:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-14T12:07:05', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'be494948-8610-4913-a509-55af78458dfd' User entered '14 Feb 2021 12:07:05'	System	14 Feb 2021 17:12:01
	System	14 Feb 2021 17:12:01

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-19T17:05:31', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27db1233-8990-4a1d-adeb-ee733b9dc4e4' User entered 'No (N)'	System	19 Feb 2021 22:05:57
	System	19 Feb 2021 22:05:57

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-19T17:05:35', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27db1233-8990-4a1d-adeb-ee733b9dc4e4' User entered 'No (N)'	System	19 Feb 2021 22:05:57

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-02-19T17:05:54', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '27db1233-8990-4a1d-adeb-ee733b9dc4e4' User entered '19 Feb 2021 17:05:54'	System	19 Feb 2021 22:05:57
	System	19 Feb 2021 22:05:57

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T17:59:54-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '43e2272f-de0a-434e-9a60-99eafc70af7e'	System	01 Mar 2021 23:00:12
User entered 'No (N)'	System	01 Mar 2021 23:00:12

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T17:59:57-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '43e2272f-de0a-434e-9a60-99eafc70af7e'	System	01 Mar 2021 23:00:12
User entered 'No (N)'	System	01 Mar 2021 23:00:12

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T18:00:05-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '43e2272f-de0a-434e-9a60-99eafc70af7e'	System	01 Mar 2021 23:00:12
User entered '01 Mar 2021 23:00:05'	System	01 Mar 2021 23:00:12

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-06T12:55:37-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '537b850b-fa56-4a16-9fe1-78c7a235ef4a'	System	06 Mar 2021 17:55:46
User entered 'No (N)'	System	06 Mar 2021 17:55:46

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-06T12:55:40-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '537b850b-fa56-4a16-9fe1-78c7a235ef4a'	System	06 Mar 2021 17:55:46
User entered 'No (N)'	System	06 Mar 2021 17:55:46

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-06T12:55:44-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '537b850b-fa56-4a16-9fe1-78c7a235ef4a' User entered '06 Mar 2021 17:55:44'	System	06 Mar 2021 17:55:46
	System	06 Mar 2021 17:55:46

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-14T15:32:03-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '58336b83-4c71-4ef9-b4b7-79097ec632ec' User entered 'No (N)'	System	14 Mar 2021 19:32:18
	System	14 Mar 2021 19:32:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-14T15:32:08-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '58336b83-4c71-4ef9-b4b7-79097ec632ec' User entered 'No (N)'	System	14 Mar 2021 19:32:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-14T15:32:15-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '58336b83-4c71-4ef9-b4b7-79097ec632ec' User entered '14 Mar 2021 15:32:15'	System	14 Mar 2021 19:32:18
	System	14 Mar 2021 19:32:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-19T10:30:10-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1686361e-68eb-4858-877f-2d604354ae9d'	System	19 Mar 2021 14:30:28
User entered 'No (N)'	System	19 Mar 2021 14:30:28

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-19T10:30:18-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1686361e-68eb-4858-877f-2d604354ae9d'	System	19 Mar 2021 14:30:28
User entered 'No (N)'	System	19 Mar 2021 14:30:28

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-19T10:30:23-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '1686361e-68eb-4858-877f-2d604354ae9d' User entered '19 Mar 2021 10:30:23'	System	19 Mar 2021 14:30:28
	System	19 Mar 2021 14:30:28

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-28T12:06:28-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '241674a2-62d4-4872-bdda-e0f93cf24aa3'	System	28 Mar 2021 16:11:18
User entered 'No (N)'	System	28 Mar 2021 16:11:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-28T12:06:34-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '241674a2-62d4-4872-bdda-e0f93cf24aa3'	System	28 Mar 2021 16:11:18
User entered 'No (N)'	System	28 Mar 2021 16:11:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-28T12:06:40-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '241674a2-62d4-4872-bdda-e0f93cf24aa3' User entered '28 Mar 2021 12:06:40'	System	28 Mar 2021 16:11:18
	System	28 Mar 2021 16:11:18

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-05T17:59:24-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '53566cf5-ba17-442d-8af9-13cca0c7f92c'	System	05 Apr 2021 21:59:37
User entered 'No (N)'	System	05 Apr 2021 21:59:37

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-05T17:59:29-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '53566cf5-ba17-442d-8af9-13cca0c7f92c'	System	05 Apr 2021 21:59:37
User entered 'No (N)'	System	05 Apr 2021 21:59:37

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-05T17:59:33-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '53566cf5-ba17-442d-8af9-13cca0c7f92c' User entered '05 Apr 2021 17:59:33'	System	05 Apr 2021 21:59:37
	System	05 Apr 2021 21:59:37

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-09T10:07:03-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '3bd2791c-503d-48d4-bcce-c3a584aca75f' User entered 'No (N)'	System	09 Apr 2021 14:07:26

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-09T10:07:17-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '3bd2791c-503d-48d4-bcce-c3a584aca75f' User entered 'No (N)'	System	09 Apr 2021 14:07:26

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-09T10:07:22-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '3bd2791c-503d-48d4-bcce-c3a584aca75f' User entered '09 Apr 2021 10:07:22'	System	09 Apr 2021 14:07:26
	System	09 Apr 2021 14:07:26

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-16T16:35:19-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6d5e055b-b095-4ab0-b250-90d0f3b61bb3'	System	16 Apr 2021 20:35:31
User entered 'No (N)'	System	16 Apr 2021 20:35:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-16T16:35:26-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6d5e055b-b095-4ab0-b250-90d0f3b61bb3'	System	16 Apr 2021 20:35:31
User entered 'No (N)'	System	16 Apr 2021 20:35:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-16T16:35:30-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '6d5e055b-b095-4ab0-b250-90d0f3b61bb3'	System	16 Apr 2021 20:35:31
User entered '16 Apr 2021 16:35:30'	System	16 Apr 2021 20:35:31

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-26T18:00:45-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2b229d6d-6d4d-4ab2-ac17-6dfd70f5a96e'	System	26 Apr 2021 22:03:25
User entered 'No (N)'	System	26 Apr 2021 22:03:25

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-26T18:00:49-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2b229d6d-6d4d-4ab2-ac17-6dfd70f5a96e'	System	26 Apr 2021 22:03:25
User entered 'No (N)'	System	26 Apr 2021 22:03:25

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-04-26T18:00:53-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2b229d6d-6d4d-4ab2-ac17-6dfd70f5a96e' User entered '26 Apr 2021 18:00:53'	System	26 Apr 2021 22:03:25
	System	26 Apr 2021 22:03:25

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-05-02T15:15:47-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2324acfc-9ef9-4524-892e-f754e9e1368b'	System	02 May 2021 19:16:04
User entered 'No (N)'	System	02 May 2021 19:16:04

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Have you been exposed to someone with 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 (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-05-02T15:15:49-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2324acfc-9ef9-4524-892e-f754e9e1368b'	System	02 May 2021 19:16:04
User entered 'No (N)'	System	02 May 2021 19:16:04

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-05-02T15:15:58-04:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: '2324acfc-9ef9-4524-892e-f754e9e1368b'	System	02 May 2021 19:16:04
User entered '02 May 2021 15:15:58'	System	02 May 2021 19:16:04

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:30:53

US3512193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:30:53
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:30:53

US3512193

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T18:00:48-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bd9d82f8-a127-4e36-8712-1431a522c09b'	System	01 Mar 2021 23:03:12
User entered 'Yes (Y)'	System	01 Mar 2021 23:03:12

US3512193

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:33

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T18:01:02-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bd9d82f8-a127-4e36-8712-1431a522c09b'	System	01 Mar 2021 23:03:12
User entered 'No (N)'	System	01 Mar 2021 23:03:12

US3512193

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (459FAAB8-77A0-4EBE-B6B9-72A062F1B657)', Time: '2021-03-01T18:01:12-05:00', User OID: 'PatientReportedOutcome (US3512193)', ODM File OID: 'bd9d82f8-a127-4e36-8712-1431a522c09b' User entered '01 Mar 2021 23:01:12'	System	01 Mar 2021 23:03:12
	System	01 Mar 2021 23:03:12

US3512193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 20:56:10

US3512193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '27 Nov 2020'	Sheldon Warren (b) (4)	27 Nov 2020 20:56:10

US3512193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 20:56:10

US3512193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 20:56:10

US3512193

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 20:56:15

US3512193

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:29
User entered 'I'	System	27 Nov 2020 20:56:15

US3512193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	04 Jan 2021 18:41:11

US3512193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '4 Jan 2021'	Sheldon Warren (b) (4)	04 Jan 2021 18:41:11

US3512193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	04 Jan 2021 18:41:11

US3512193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	04 Jan 2021 18:41:11

US3512193

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	04 Jan 2021 18:41:16

US3512193

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered 'I'	System	04 Jan 2021 18:41:16

US3512193

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 21:36:33

US3512193

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '28 Jan 2021'	Sheldon Warren (b) (4)	28 Jan 2021 21:36:33

US3512193

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 21:36:33

US3512193

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 21:36:33

US3512193

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 21:36:25

US3512193

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered 'I'	System	28 Jan 2021 21:36:25

US3512193

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:00:39
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Feb 2021 17:47:17

US3512193

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:00:39
User entered '26 Feb 2021'	Sheldon Warren (b) (4)	26 Feb 2021 17:47:17

US3512193

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:00:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	26 Feb 2021 17:47:17

US3512193

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:00:39
User entered empty.	(b) (4) Sheldon Warren (b) (4)	26 Feb 2021 17:47:17

US3512193

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:00:39
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Feb 2021 17:47:22

US3512193

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered 'I'	System	26 Feb 2021 17:47:22

US3512193

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 18:58:02

US3512193

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 18:58:02

US3512193

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	31 Mar 2021 18:58:02

US3512193

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered 'VISIT4'	System	31 Mar 2021 18:58:02

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered empty.	System	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered empty.	System	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered empty.	System	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered empty.	System	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered empty.	System	31 Mar 2021 18:58:15

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12

US3512193

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12

US3512193

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'No (N)'	Brenda Anderson (b) (4)	31 Mar 2021 18:58:21

US3512193

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered empty.	Brenda Anderson (b) (4)	31 Mar 2021 18:58:21

US3512193

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 18:59:46

US3512193

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered '31 Mar 2021'	Brenda Anderson (b) (4)	31 Mar 2021 18:59:46

US3512193

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered '10:18'	Brenda Anderson (b) (4)	31 Mar 2021 18:59:46

US3512193

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered '31 Mar 2021 10:18'	System	31 Mar 2021 18:59:46

US3512193

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:29:35
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	31 Mar 2021 18:59:52

US3512193

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:03:12
User entered 'I'	System	31 Mar 2021 18:59:52

US3512193

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:39
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	27 Apr 2021 19:39:58
	(b) (4)	

US3512193

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:39
	(b) (4)	
User entered '27 Apr 2021'	Sheldon Warren (b) (4)	27 Apr 2021 19:39:58
	(b) (4)	

US3512193

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	27 Apr 2021 19:39:58

US3512193

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:39
User entered empty.	(b) (4) Sheldon Warren (b) (4)	27 Apr 2021 19:39:58
	(b) (4)	

US3512193

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:39
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	27 Apr 2021 19:40:03
	(b) (4)	

US3512193

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:40:03

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 23:10:36
User closed query 'Per source visit date is 23OCT2020. Please review and update accordingly ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 23:10:33
Query 'Per source visit date is 23OCT2020. Please review and update accordingly ' answered with 'updated' (Site from CRA).	Allison Crain (b) (4)	16 Mar 2021 16:39:46
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	16 Mar 2021 16:39:39
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	16 Mar 2021 16:39:39
User opened query 'Per source visit date is 23OCT2020. Please review and update accordingly ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 21:42:33
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (23Oct 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:14:54
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (23Oct 2020). Please review and reconcile.' answered with 'updated' (Site from DM).	Allison Crain (b) (4)	26 Jan 2021 14:23:51
	(b) (4)	
User entered '22 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:03:15
	(b) (4)	
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (23Oct 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:00:55

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:49:52
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'added' (Site from DM).	Allison Crain (b) (4)	13 Nov 2020 13:39:07
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 23 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:31:46
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	04 Nov 2020 21:57:27

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:37
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:23:45
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 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:39:27
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 13:32:24
User entered '10:00'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 21:57:27

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:05
User entered '23 Oct 2020 10:00'	System	16 Mar 2021 16:39:39
User entered '22 Oct 2020 10:00'	System	26 Jan 2021 13:03:15
User entered '23 Oct 2020 10:00'	System	04 Nov 2020 21:57:27

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:39
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 21:57:27

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 21:57:27

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 1 (Day 1)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '21 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:10:08
User entered '23 Oct 2020'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Jan 2021 13:10:08
User entered '98'	Allison Crain (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Jan 2021 13:10:08
User entered '100.0' F	Allison Crain (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:11:43
User entered 'Mild (Mild)'	Allison Crain (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Allison Crain (b) (4)	26 Jan 2021 13:10:08
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:10:08
User entered 'Moderate (Moderate)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:10:08
User entered 'Moderate (Moderate)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:10:08
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:10:08
User entered 'Mild (Mild)'	Allison Crain (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 2 (Day 2)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:13:55
User entered '24 Oct 2020'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Jan 2021 13:13:55
User entered '94'	Allison Crain (b) (4)	04 Nov 2020 22:20:19
	Brenda Anderson (b) (4)	
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '100.4' F reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:13:55
User entered '99.1' F	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Severe (Severe)' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:13:55
User entered 'Mild (Mild)'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:13:55
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:13:55
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:13:55
User entered 'None (None)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 3 (Day 3)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
User entered '25 Oct 2020'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
	(b) (4)	
User entered '97'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '100.0' F reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
User entered '98.7' F	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
	(b) (4)	
User entered 'Mild (Mild)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
User entered 'Mild (Mild)'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
User entered 'Mild (Mild)'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:15:00
User entered 'None (None)'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 4 (Day 4)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '24 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:16:30
User entered '26 Oct 2020'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '94' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:16:30
User entered '96'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '99.1' F reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:16:30
User entered '98.2' F	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:16:30
User entered 'None (None)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:19

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:16:30
User entered 'None (None)'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 5 (Day 5)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '25 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered '27 Oct 2020'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '97' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered '85'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98.7' F reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered '98.3' F	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Per CDM : It appears some data is missing for day 5. Please review and update accordingly.' (Site from DM).	(b) (4)	
Query 'Per CDM : It appears some data is missing for day 5. Please review and update accordingly.'	(b) (4), (b) (6)	28 Jan 2021 04:15:18
answered with 'UPDATED' (Site from DM).		
User entered 'None (None)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:57
User opened query 'Per CDM : It appears some data is missing for day 5. Please review and update accordingly.' (Site from DM).	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:17:50
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:17:50
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered 'Moderate (Moderate)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:17:50
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:17:50
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
	(b) (4)	
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:17:50
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:19
DataPoint activated with code reason code Data required.	Brenda Anderson (b) (4)	04 Nov 2020 22:13:23
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:00:21

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 6 (Day 6)'	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '26 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:19:11
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:20:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:20:52
User entered '28 Oct 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Nov 2020 22:20:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:20:39
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'I'	(b) (4) Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:19:11
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	26 Jan 2021 13:19:11
User entered empty.	System	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:19:11
User entered empty.	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Allison Crain (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Allison Crain (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Allison Crain (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 13:19:11
User entered empty.	Allison Crain (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 13:19:11
	(b) (4)	
	Brenda Anderson (b) (4)	04 Nov 2020 22:20:39
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Day 7 (Day 7)'	Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '27 Oct 2020'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '0'	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:20:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Allison Crain (b) (4)	26 Jan 2021 13:19:27
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:24:51
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '85'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
User entered '%'	System	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '98.3' F	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Moderate (Moderate)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Mild (Mild)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4)	
	Allison Crain (b) (4)	26 Jan 2021 13:20:39
	(b) (4)	
DataPoint activated with code reason code Data required.	Allison Crain (b) (4)	26 Jan 2021 13:19:27
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4)	04 Nov 2020 22:24:51
	(b) (4)	

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:03:33

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:16:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'None (None)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:20:39
DataPoint activated with code reason code Data required.	(b) (4) Allison Crain (b) (4)	26 Jan 2021 13:19:27
DataPoint inactivated with code reason code Data not required.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:24:51

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:03:33

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:57
User entered '0'	System	13 Nov 2020 13:27:00

US3512193

Folder: Covid-19 Assessment 23 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:03:33

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:15:54
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:42:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:27:15

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '25 Oct 2020'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:03:33

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:03:33

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:35:44

US3512193

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4)	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered 'SICKD1'	System	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:34'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered '23 Oct 2020 10:34'	System	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '63.25' in	(b) (4) Allison Crain (b) (4)	13 Nov 2020 13:28:32
DataPoint set to visible.	(b) (4) System	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '132.4' lb	(b) (4) Allison Crain (b) (4)	13 Nov 2020 13:28:32
DataPoint set to visible.	(b) (4) System	13 Nov 2020 13:27:28

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '100.0' F reason for change: Data Entry Error	System	13 Nov 2020 13:28:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Allison Crain (b) (4)	13 Nov 2020 13:28:54
User entered '100' (non-conformant).	(b) (4)	
	System	13 Nov 2020 13:28:32
	Allison Crain (b) (4)	13 Nov 2020 13:28:32
	(b) (4)	

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:59
Query 'Data is required. Please provide.' answered by System	System	13 Nov 2020 13:28:59
data change (Site from System).		13 Nov 2020 13:28:59
User entered 'Oral (Oral)' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:28:59
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:54
User entered empty.	System	13 Nov 2020 13:28:54
	Allison Crain (b) (4)	13 Nov 2020 13:28:32
	(b) (4)	

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 13:28:54
User entered '83' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:28:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:32
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered 'bpm'	System	13 Nov 2020 13:28:54
User entered empty.	System	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 13:28:54
User entered '14' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:28:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:32
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered 'breaths/min'	System	13 Nov 2020 13:28:54
User entered empty.	System	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 13:28:54
User entered '117' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:28:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:32
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered 'mmHg'	System	13 Nov 2020 13:28:54
User entered empty.	System	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 13:28:54
User entered '69' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:28:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 13:28:32
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
User entered 'mmHg'	System	13 Nov 2020 13:28:54
User entered empty.	System	13 Nov 2020 13:28:32

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57

US3512193

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57

US3512193

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:18
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:29:13

US3512193

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:18
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:29:13

US3512193

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:03:33

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:29:21

US3512193

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:03:33

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '23 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:29:21

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:46

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Jan 2021'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:46

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:46

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 12:57:46

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:38
User entered '0'	(b) (4) Allison Crain (b) (4)	08 Apr 2021 13:31:12
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:31:43

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:38
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 05:20:29
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	08 Apr 2021 13:31:46
User entered 'Amendment 6 or later (Amendment 6 or later)'	Allison Crain (b) (4) (b) (4)	08 Apr 2021 13:31:12
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:28:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:31:43

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Jan 2021'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'No (N)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User entered empty.	System	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User entered empty.	System	25 Jan 2021 12:57:36

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:14

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Jan 2021'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:14

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:45'	Brenda Anderson (b) (4)	25 Jan 2021 12:57:14

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User entered '22 Jan 2021 10:45'	System	25 Jan 2021 12:57:14

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	25 Jan 2021 12:56:58

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '22 Jan 2021'	Brenda Anderson (b) (4)	25 Jan 2021 12:56:58

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10:35'	Brenda Anderson (b) (4)	25 Jan 2021 12:56:58

US3512193

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:33:08
User entered '22 Jan 2021 10:35'	System	25 Jan 2021 12:56:58

US3512193

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:06:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	26 Oct 2020 19:45:39
User entered 'No (N)'	(b) (4)	
	Allison Crain (b) (4)	02 Oct 2020 15:26:01
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:49:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:49:46
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 19:48:03
User entered 'fatigue'	Sheldon Warren (b) (4)	26 Oct 2020 19:47:37
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '23 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Applicable (NOT APPLICABLE)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'I'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 19:47:37

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:29:54
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:08:43
User entered	System	05 Nov 2020 19:08:35
'USA-US065-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	05 Nov 2020 19:08:35

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:33:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:33:31
Data point term sent to Coder	System	04 Nov 2020 22:32:05
User entered 'atrial fibrillation'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per SAE Recon: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:53:04
Query 'Per SAE Recon: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	25 Nov 2020 20:51:17
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	25 Nov 2020 20:51:08
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	25 Nov 2020 20:51:08
User opened query 'Per SAE Recon: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 17:33:24
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '27 Oct 2020'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	Allison Crain (b) (4)	09 Dec 2020 15:30:52
User entered 'No (N)' reason for change: New Information	Allison Crain (b) (4)	09 Dec 2020 15:30:52
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:55:30
Query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Dec 2020 15:31:34
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Dec 2020 15:31:14
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Dec 2020 15:31:14
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Dec 2020 15:30:52
User entered '6 Nov 2020' reason for change: New Information	Allison Crain (b) (4) (b) (4)	09 Dec 2020 15:30:52
User opened query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:24:59

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:24:45
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:24:35
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 16:15:52
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' answered with 'Considered ongoing condition' (Site from Safety).	Allison Crain (b) (4) (b) (4)	25 Nov 2020 20:51:44
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:24:34
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:27:00

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'AE is still ongoing. Data confirmed as is' (Site from Safety).	Taylor Johnson (b) (4)	21 Nov 2020 21:31:51
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:19:32
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 01:38:42
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'still ongoing' (Site from Safety).	Brenda Anderson (b) (4)	16 Nov 2020 15:24:41
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:58
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:07:40
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Nov 2020 22:32:17
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Nov 2020 22:31:33
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		13 Nov 2020 13:01:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		13 Nov 2020 13:01:36
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	04 Nov 2020 22:32:17
User entered '1' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Nov 2020 22:32:17
User entered '0'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:31:33
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '27 Oct 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:22:48
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 16:28:35
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Allison Crain (b) (4)	11 Nov 2020 20:36:04
	(b) (4)	
User entered '30 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	11 Nov 2020 20:34:53
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:08:29
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:01:36
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Nov 2020 13:01:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Nov 2020 22:31:33
User entered '0'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '1' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:01:57
User entered '0'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered '1' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:01:57
User entered '0'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:55:38
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'updated' (Site from Safety).	Allison Crain (b) (4) (b) (4)	09 Dec 2020 15:40:11
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	09 Dec 2020 15:31:14
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:47:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:44:17
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available. ' answered with 'Subject is expected to remain on afib medication sotalol long term. This ae is not expected to resolve. Data confirmed as is. Please contact sites CRA (b) (6) for any updates the study team might need regarding this matter. The site requests that this query remains closed.' (Site from Safety).	Taylor Johnson (b) (4) (b) (4)	04 Dec 2020 13:31:50

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:25:35
User closed query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:27:08
Query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Data confirmed as is. Investigator reevaluated AE on 17Nov2020 and determined that it is still ongoing. Status of symptoms will be reevaluated at each follow up contact. AE will remain open for now ' (Site from Safety).	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 21:41:33
User opened query ' PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:19:44
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 14:07:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'unknown, will evaluate throughout trial.' (Site from Safety).	Brenda Anderson (b) (4) (b) (4)	18 Nov 2020 12:43:53
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 14:30:06
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 13:02:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 13:02:43

PRODUCTION RELEASE (v12.003
EAB) (1725)

2437 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:02:43
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	06 Nov 2020 15:07:58
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:31:33
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'SUBJECT NOW HAS ONGOING ATRIAL FIBRILLATION, NO LONGER A SERIOUS ADVERSE EVENT.' reason for change: Data Entry Error	Allison Crain (b) (4)	09 Dec 2020 15:45:42
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	09 Dec 2020 15:40:59
DataPoint Un-verified.	Allison Crain (b) (4)	09 Dec 2020 15:40:59
User entered 'Subject now has ongoing Atrial Fibrillation.' reason for change: Data Entry Error	Allison Crain (b) (4)	09 Dec 2020 15:40:59
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	09 Dec 2020 15:31:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:29:54
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:29:54
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:26:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:26:41
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' answered with 'Submitted' (Site from Safety).	Allison Crain (b) (4) (b) (4)	14 Nov 2020 19:10:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Submitted' (Site from Safety).	Allison Crain (b) (4) (b) (4)	14 Nov 2020 19:10:18
Comment added 'Per monitor (b) (6) she will be in on Monday and will review the redacted discharge summary and labs.'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 16:20:03
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications and procedures added to appropriate eCRF.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:37:21

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:09:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:08:15
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:08:09
User entered 'PT IN CoNVALESCENT PERIOD STARTING WITH ILLNESS VISIT ON 23 OCT 2020. 27-OCT-2020 PT CALLED SITE WITH PULSE OX OF 91% SOON AFTER WAKING. IT WAS RECOMMEDED THAT SHE GET UP AND MOVE AROUND and REPEAT HER PULSE OX. AT 12:21 PM PT REPORTED A PULSE OX OF 85%. SUBJECT ALSO had SHORTNESS OF BREATH AND TERRIBLE HEADACHE. DR. (b) (6) (SUB-I) RECOMMENDED THAT SHE CONTACT HER PCP AND INFORM THEM OF HER SYMPTOMS. PT WAS INSTRUCTED THAT iF PCP WAS NOT AVAILABLE TO SEEK MEDICAL ATTENTION. PT HAD COVID TEST AT HOSPITAL NEGATIVE.. Pt diagnosed with Atrial fibrillation.' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:04:34
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 13:02:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 13:02:38

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'pt in cnvalescent period starting with illness visit on 23 Oct 2020. 27-Oct-2020 pt called site with Pulse ox of 91% soon after waking. It was recommended that she get up and move around repeat her pulse ox. At 12:21 pm pt reported a pulse ox of 85%. Subject also shortness of breath and Terrible headache. Dr. (b) (6) (sub-I) recommended that she contact her PCP and inform them of her symptoms. Pt was instructed that PCP was not available to seek medical attention. Pt had COVID test at hospital negative.' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:02:38
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Nov 2020 22:31:33
User entered empty.	Brenda Anderson (b) (4)	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 22:31:33

US3512193

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 13:01:36

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Sinusitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 08:01:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:05:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:05:50
Data point term sent to Coder	System	26 Jan 2021 18:43:55
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Sinusitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Jan 2021 18:43:33
Coding entries removed.	Allison Crain (b) (4) (b) (4)	26 Jan 2021 18:43:24
User entered 'WORSENER INTERMITTENT SINUSITIS' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Jan 2021 18:43:24
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Sinusitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:02:24
User closed query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, 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 Dec 2020 09:42:25

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, 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 'NO illness visit required per Sub investigator, continuation of previous symptoms.' (Site from DM).	Brenda Anderson (b) (4)	16 Dec 2020 17:41:25
User opened query 'Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 06:19:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 16:53:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 16:53:45
Data point term sent to Coder	System	16 Nov 2020 16:52:58
User entered 'Acute Sinusitis'	Sheldon Warren (b) (4)	16 Nov 2020 16:52:43
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '2 Nov 2020'	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
User entered empty.	System	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '5 Nov 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
User entered empty.	System	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'l'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
User entered '0'	System	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34
User entered '0'	System	16 Nov 2020 16:52:43

US3512193

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:34

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per MM:Please confirm if this does not meet the definition of an SAE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 10:21:20
Query 'Per MM:Please confirm if this does not meet the definition of an SAE.' answered with 'Please see SAE, AE log #9' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:32:43
User opened query 'Per MM:Please confirm if this does not meet the definition of an SAE.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 08:23:01
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 16:07:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 16:07:01
Data point term sent to Coder	System	09 Dec 2020 16:06:06
User entered 'ATRIAL FIBRILLATION'	Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '7 Nov 2020'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 05:56:27
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	14 Feb 2021 18:30:24
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	14 Feb 2021 18:30:17
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:18:14
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '9 Dec 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	14 Feb 2021 18:30:17
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #22, 23 and 24 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 05:43:50
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #22, 23 and 24 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'These meds were related to SAE of Atrial Fibrillation, which are still taken for this AE.' (Site from DM).	Allison Crain (b) (4)	16 Mar 2021 17:04:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #22, 23 and 24 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:54:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'I'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'I'	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	14 Feb 2021 18:30:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Allison Crain (b) (4)	09 Dec 2020 16:05:12
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 16:05:12

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fractured toe - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 15:21:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 15:21:19
Data point term sent to Coder	System	25 Jan 2021 13:05:31
User entered 'right middle toe fracture'	Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '26 Nov 2020'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
User entered empty.	System	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '26 Dec 2020'	(b) (4) Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
User entered empty.	System	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'l'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
User entered '0'	System	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42
User entered 'I'	System	25 Jan 2021 13:05:06

US3512193

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:42

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
User closed query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:01:23
Query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' answered with 'Not Covid-19 per testing. Unknown organism.' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Mar 2021 16:04:26
User opened query 'Per MM: please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:23:41
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Intermittent Urinary Tract Infections. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 04:44:39
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Intermittent Urinary Tract Infections. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Please see updated AE term' (Site from DM).	Allison Crain (b) (4) (b) (4)	04 Mar 2021 18:54:57
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Intermittent Urinary Tract Infections. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:43:36
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Feb 2021 18:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Feb 2021 18:16:43

PRODUCTION RELEASE (v12.003
EAB) (1725)

2554 of 3165

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Feb 2021 18:16:31
Coding entries removed.	Allison Crain (b) (4)	14 Feb 2021 18:16:10
	(b) (4)	
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Allison Crain (b) (4)	14 Feb 2021 18:16:10
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 17:37:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 17:37:51
	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 17:35:31
User entered 'URINARY TRACT INFECTION'	Allison Crain (b) (4)	26 Jan 2021 17:34:51
	(b) (4)	

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '21 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
User entered empty.	System	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '5 Nov 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
User entered empty.	System	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	Allison Crain (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	Allison Crain (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Allison Crain (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'l'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 21:43:58
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
User entered '0'	System	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55
User entered '0'	System	26 Jan 2021 17:34:51

US3512193

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:58:55

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 08:30:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 08:30:48
Data point term sent to Coder	System	16 Mar 2021 22:14:52
User entered 'Actinic Keratosis (right and left mid-cheek furrow, Left palpebromalar groove, right lower vermillion border)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'No (N)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'No (N)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '23 Feb 2021'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 22:14:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 22:14:20
User entered 'No (N)' reason for change: Data Entry Error	Sheldon Warren (b) (4)	16 Mar 2021 22:14:20
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 22:14:12
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '23 Feb 2021'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'No (N)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered '0'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'I'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:10
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:45
User entered empty.	Sheldon Warren (b) (4)	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 22:14:12

US3512193

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 22:14:12

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:33

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:21
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:51:35
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'updated' (Site from DM).	Sheldon Warren (b) (4) (b) (4)	01 Apr 2021 20:55:31
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:21:17
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:06:37
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:53:42

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
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) (b) (4)	02 Sep 2020 17:55:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:55:44
Data point term sent to Coder	System	02 Sep 2020 17:54:42
User entered 'LEVOTHYROXINE'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '75'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ug (ug)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 1990'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:54:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:56:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:56:49
Data point term sent to Coder	System	02 Sep 2020 17:55:43
User entered 'LYOTHYRONINE'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '5'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ug (ug)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2017'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:55:21

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:57:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:57:54
Data point term sent to Coder User entered 'LISINOPRIL'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:56:45 02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'HYPERTENSION'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '60'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2014'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:55:52

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 19:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:24:43
Data point term sent to Coder	System	17 Dec 2020 13:35:43
Coding entries removed.	Brenda Anderson (b) (4)	17 Dec 2020 13:34:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 13:26:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 13:26:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 23:40:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 23:40:43

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 12:23:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 12:23:46
Data point term sent to Coder	System	03 Sep 2020 22:28:49
Data point term sent to Coder	System	02 Sep 2020 17:57:50
User entered 'FLUTICASONE NASAL SPRAY'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SINUSITIS' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:28:26
User entered 'ALLERGIES/SINUSITIS'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of Sprays, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:11:05
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of Sprays, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:08:52
User entered '100' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:08:43
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of Sprays, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:48:44
User entered '2'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ug (ug)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:08:43
User entered 'Other (OTHER)'	Allison Crain (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:08:43
User entered 'PUFF PER NOSTRIL'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 09:55:35
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	17 Dec 2020 13:34:51
DataPoint Un-verified.	Brenda Anderson (b) (4) (b) (4)	17 Dec 2020 13:34:45
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	17 Dec 2020 13:34:45
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:00:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
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 MH condition. Please reconcile and update applicable details as appropriate. Otherwise , clarify.' (Site from DM). 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 MH condition. Please reconcile and update applicable details as appropriate. Otherwise , clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:23:52
User entered 'UN UNK 2015' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:08:59
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 MH condition. Please reconcile and update applicable details as appropriate. Otherwise , clarify.' (Site from DM). User entered 'UN UNK 2014'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:08:43
	(b) (4), (b) (6)	12 Oct 2020 13:48:51
	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 17:57:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:59:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:59:48
Data point term sent to Coder	System	02 Sep 2020 17:58:52
User entered 'SUMATRIPTAN'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Per DM CLR: Indication of Migraine was noted. However, the corresponding MH record was listed as resolved since 1990 and this medication was given after the date of resolution. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:05:24
Query 'Per DM CLR: Indication of Migraine was noted. However, the corresponding MH record was listed as resolved since 1990 and this medication was given after the date of resolution. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' answered with 'changed MH' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:14:47
User opened query 'Per DM CLR: Indication of Migraine was noted. However, the corresponding MH record was listed as resolved since 1990 and this medication was given after the date of resolution. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:49:46
User entered 'MIGRAINES'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '50'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2000'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 17:57:56

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: OTHER OPHTHALMOLOGICALS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 16:30:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 16:30:00
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: OTHER OPHTHALMOLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 15:59:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 15:59:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ASCORBIC ACID;CUPRIC OXIDE;DL-ALPHA TOCOPHERYL ACETATE;XANTOXYL;ZEAXANTHIN;ZINC OXIDE, PRODUCTS YNOM: PRESERVATION AREDS 2 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:34:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 05:34:44
Data point term sent to Coder	System	02 Sep 2020 18:00:58
User entered 'AREDS 2'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'GLAUCOMA/MACULAR DEGENERATION'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'I'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'tablet (TABLET)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:00:32

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:02:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:02:49
Data point term sent to Coder	System	02 Sep 2020 18:02:00
User entered 'CALCIUM WITH VITAMIN D'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:13
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 06:29:18
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. ' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:28:28
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:28:18
User entered '1200/1000' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:28:18
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:04:36
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '1000'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:01:23

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: RESVERATROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:03:51
Data point term sent to Coder User entered 'RESVERATROL'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:03 02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:20
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '500'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:02:03

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:03:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:03:50
Data point term sent to Coder	System	02 Sep 2020 18:03:08
User entered 'MULTIVITAMIN'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'I'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'tablet (TABLET)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:02:49

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 12:30:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 12:30:49
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3 FATTY ACIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 18:05:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 18:05:43
	(b) (4)	
Data point term sent to Coder User entered 'OMEGA 3'	System	02 Sep 2020 18:04:09
	Allison Crain (b) (4)	02 Sep 2020 18:03:18
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:35
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '2100'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:03:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:05:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:05:44
Data point term sent to Coder User entered 'VITAMIN D3'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:11 02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:43
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:33:25
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' answered with 'unknown, pt reported tablets' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:15:21
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:53:34
User entered 'I'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'tablet (TABLET)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'every other day (QOD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:04:00

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B COMPLEX PLUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 18:51:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 18:51:52
Data point term sent to Coder	System	02 Sep 2020 18:05:12
User entered 'B COMPLEX PLUS'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:04:50
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'I'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'tablet (TABLET)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:04:37

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:06:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:06:48
Data point term sent to Coder User entered 'MIRALAX'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:15 02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'CONSTIPATION'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:21:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:21:53
User entered '17' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:21:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:06:04
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:21:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:21:53
User entered 'g (g)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:21:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:06:04
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN UNK 2015'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:06:04

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 18:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 18:07:47
Data point term sent to Coder	System	02 Sep 2020 18:07:20
User entered 'VITAMIN C'	Allison Crain (b) (4)	02 Sep 2020 18:06:59
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	13 Nov 2020 14:09:50
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SUPPLEMENT'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:32:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' answered with 'unknown at this time' (Site from DM).	Allison Crain (b) (4) (b) (4)	12 Nov 2020 21:57:51
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:50:16
User entered 'I'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'tablet (TABLET)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:27:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:27:06
User entered 'once daily (QD)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:27:06
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:06:59
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '15 Aug 2020'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:27:06
User entered empty.	System	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 22:27:06
User entered empty.	System	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 22:27:06
User entered empty.	System	02 Sep 2020 18:06:59

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:46
Data point term sent to Coder User entered 'ALEVE'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:21 02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'OSTEOARTHRITIS'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '220'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 22:27:23
User entered 'UN UNK 2013' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:27:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 18:07:34
User entered 'UN UNK ' (non-conformant).	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:07:34

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:08:47
Data point term sent to Coder User entered 'MUCINEX'	System Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:23 02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'SINUSITIS'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '600'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 22:28:08
User entered 'UN UNK 2015' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:28:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 18:08:18
User entered 'UN UNK ' (non-conformant).	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 18:08:18

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Nov 2020 06:10:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:10:16
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4)	19 Nov 2020 17:25:28 19 Nov 2020 17:24:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 08:43:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 08:43:38
Data point term sent to Coder User entered 'TRIAMCINOLONE 0.1%'	System Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:42:13 03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review Indication and please update to specify the location of Contact Dermatitis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 06:10:53
DataPoint Un-verified.	Brenda Anderson (b) (4)	19 Nov 2020 17:24:55
User entered 'CONTACT DERMATITIS bilateral arm' reason for change: New Information	(b) (4) Brenda Anderson (b) (4)	19 Nov 2020 17:24:55
Query 'Per DM CLR: Please review Indication and please update to specify the location of Contact Dermatitis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'bilateral arms' (Site from DM).	(b) (4) Brenda Anderson (b) (4)	19 Nov 2020 17:24:42
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of Contact Dermatitis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:43:04
User entered 'CONTACT DERMATITIS'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '2'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Other (OTHER)'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'APPLICATIONS'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Topical (TOPICAL)'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 22:42:03
User entered '02 Mar 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:42:03
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 22:41:47
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:42:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:42:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:42:03
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:41:47
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:42:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 22:42:03
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:42:03
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 22:41:47
User entered empty.	Allison Crain (b) (4) (b) (4)	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 22:41:47

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:15:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:15:41
Data point term sent to Coder	System	02 Oct 2020 23:43:33
User entered 'Ciprofloxacin'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'intermittent urinary tract infection'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '500'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 03:53:53
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.	Brenda Anderson (b) (4) (b) (4)	25 Jan 2021 13:14:57
' answered with 'per patient' (Site from DM).		
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:10:46
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	16 Nov 2020 14:08:27
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'UN Sep 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:21:47
User entered 'UN UNK 2015'	(b) (4)	
	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:15:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:15:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:15:14
User entered '4 Oct 2020' reason for change: Data Entry Error	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:15:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User entered empty.	System	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User entered empty.	System	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:45
User entered empty.	System	02 Oct 2020 23:43:08

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
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)	25 Jan 2021 13:15:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 13:15:52
Data point term sent to Coder	System	25 Jan 2021 13:14:32
Coding entries removed.	Brenda Anderson (b) (4)	25 Jan 2021 13:14:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
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)	19 Oct 2020 19:28:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:28:26
Data point term sent to Coder	System	19 Oct 2020 19:27:41
User entered 'influenza vaccine'	Sheldon Warren (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:14:08
User entered 'prophylaxis for SEASONAL INFLUENZA' reason for change: Data Entry Error	(b) (4) Brenda Anderson (b) (4)	25 Jan 2021 13:14:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'seasonal influenza'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'l'	Sheldon Warren (b) (4)	19 Oct 2020 19:27:13
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Other (OTHER)'	Sheldon Warren (b) (4)	19 Oct 2020 19:27:13
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'injection'	Sheldon Warren (b) (4)	19 Oct 2020 19:27:13
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once (ONCE)'	Sheldon Warren (b) (4)	19 Oct 2020 19:27:13
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Intramuscular (INTRAMUSCULAR)'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '19 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '19 Oct 2020'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User entered empty.	System	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User entered empty.	System	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:18:35
User entered empty.	System	19 Oct 2020 19:27:13

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 17:59:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	26 Jan 2021 17:59:54
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	26 Jan 2021 17:58:58 26 Jan 2021 17:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 20:33:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	26 Oct 2020 20:33:30
Data point term sent to Coder User entered 'aleve'	System Sheldon Warren (b) (4)	26 Oct 2020 19:45:58 26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 05:37:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'UPDATED AE name please review' (Site from DM).	Allison Crain (b) (4) (b) (4)	14 Feb 2021 18:17:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 13:51:13
User closed query 'Per DM CLR: Please review Sore Throat and Fever as these does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:05:42
Query 'Per DM CLR: Please review Sore Throat and Fever as these does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'UPDATED' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:58:19
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:58:01
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Jan 2021 17:58:01

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Sore Throat and Fever as these does not indicate “Other Action Taken = Concomitant Medication”, please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 07:12:30
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'headache, sore throat, low grade fever, muscle aches'	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 06:29:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:29:39
User entered '220' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:29:32
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:29:18
User entered '440' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Jan 2021 14:29:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:14:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '420'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'as needed (PRN)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '22 Oct 2020'	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:05:29
DataPoint Un-verified.	Allison Crain (b) (4)	26 Jan 2021 17:58:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	Allison Crain (b) (4)	26 Jan 2021 17:58:28
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 07:14:36
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	26 Jan 2021 17:58:28
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Jan 2021 17:58:12
DataPoint Un-verified.	Allison Crain (b) (4)	26 Jan 2021 17:58:12
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 17:58:12
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Sheldon Warren (b) (4)	26 Oct 2020 19:45:22
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User entered empty.	System	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User entered empty.	System	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:14:37
User entered empty.	System	26 Oct 2020 19:45:22

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:16:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:16:44
Data point term sent to Coder	System	13 Nov 2020 13:15:39
User entered 'PREDNISONE'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'SINUSITIS'	Allison Crain (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '5'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'once daily (QD)'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '2 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '6 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:15:31
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User entered '1'	System	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User entered '1'	System	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:47:47
User entered '804 (804)'	System	13 Nov 2020 13:15:31

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:18:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:18:43
Data point term sent to Coder	System	13 Nov 2020 13:17:40
User entered 'ELIQUIS'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ATRIAL FIBRILLATION'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '5'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '30 Oct 2020'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 13:16:51

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:18:44
Data point term sent to Coder	System	13 Nov 2020 13:17:41
User entered 'METOPROLOL'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ATRIAL FIBRILLATION'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '25'	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once daily (QD)'	Allison Crain (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 13:17:53
User entered '30 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:53
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 13:17:30
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4)	13 Nov 2020 13:17:30
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 13:17:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 13:17:53
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 13:17:30
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '6 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	13 Nov 2020 13:17:53
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 13:17:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 13:17:53
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:53
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 13:17:30
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User entered '1'	System	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User entered '1'	System	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:35:00
User entered '804 (804)'	System	13 Nov 2020 13:17:30

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:19:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:19:44
Data point term sent to Coder	System	13 Nov 2020 13:18:41
User entered 'SOTALOL'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'ATRIAL FIBRILLATION'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '80'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'mg (mg)'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'twice daily (BID)'	Allison Crain (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '6 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered '0'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	(b) (4) Allison Crain (b) (4)	09 Dec 2020 16:06:10
User entered 'No (N)' reason for change: New Information	(b) (4) Allison Crain (b) (4)	09 Dec 2020 16:06:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:27
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Un-verified.	(b) (4)	
	Allison Crain (b) (4)	09 Dec 2020 16:06:10
User entered '3 Dec 2020' reason for change: New Information	(b) (4)	09 Dec 2020 16:06:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:18:35
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User entered '2'	System	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User entered '1'	System	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:51:24
User entered '804 (804)'	System	13 Nov 2020 13:18:35

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:24:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:24:47
Data point term sent to Coder	System	13 Nov 2020 13:23:44
User entered 'DOXYCYCLINE'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'SINUSITIS'	Allison Crain (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '100'	Allison Crain (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'twice daily (BID)'	Allison Crain (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered empty.	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '2 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '11 Nov 2020'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:08:27
User entered 'No (N)'	Allison Crain (b) (4)	13 Nov 2020 13:23:28
	(b) (4)	

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User entered '2'	System	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User entered '1'	System	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:32:30
User entered '804 (804)'	System	13 Nov 2020 13:23:28

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:03:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:09:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	05 Nov 2020 13:23:01
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	02 Oct 2020 15:26:06

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:10:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:42:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 21:42:55
User entered '28 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Nov 2020 21:42:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 13:23:36
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 13:23:36
	(b) (4)	

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:10:40
User entered 'Echocardiogram'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:23:36

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:10:40
User entered 'Adverse Event (AE)'	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:23:36

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:10:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	05 Nov 2020 13:23:36

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4)	16 Nov 2020 14:10:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 21:55:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 21:55:58
User entered '29 Oct 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Nov 2020 21:55:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 13:24:01
User entered empty.	System	05 Nov 2020 13:24:01
	Brenda Anderson (b) (4)	05 Nov 2020 13:24:01
	(b) (4)	

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:10:40
User entered 'cardioversion'	Brenda Anderson (b) (4)	05 Nov 2020 13:24:01

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 14:10:40
User entered 'Adverse Event (AE)'	Brenda Anderson (b) (4)	05 Nov 2020 13:24:01
	(b) (4)	

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:53
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
DataPoint Verified.	(b) (4)	16 Nov 2020 14:10:40
User entered empty.	Brenda Anderson (b) (4)	05 Nov 2020 13:24:01

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered '13 Nov 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:41

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered 'CARDIOVERSION'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:41

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered 'Adverse Event (AE)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:41

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:41

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered '9 Dec 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:58

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered 'CRYOBALLOON ABLATION'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:58

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered 'Adverse Event (AE)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:58

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:33:07
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Dec 2020 16:07:58

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:27
User entered '23 Feb 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Mar 2021 22:11:42

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:27
User entered 'cryotherapy'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Mar 2021 22:11:42

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:27
User entered 'Adverse Event (AE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Mar 2021 22:11:42

US3512193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:08:40
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	16 Mar 2021 22:11:42

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'USA-US065-2020-MRNA-1273-P301000002'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Michael'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Koren'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'US'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User entered '4'	System	10 Dec 2020 20:56:06
User entered '3'	System	16 Nov 2020 14:29:11
User entered '2'	System	12 Nov 2020 16:29:12
User entered '1'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'USA-US065-2020-MRNA-1273-P301000002'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Michael'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Koren'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'US'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User entered '4'	System	10 Dec 2020 20:56:06
User entered '3'	System	16 Nov 2020 14:29:11
User entered '2'	System	12 Nov 2020 16:29:12
User entered '1'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
User entered '05/Nov/2020 19:11'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'USA-US065-2020-MRNA-1273-P301000002'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Michael'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Koren'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'US'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User entered '4'	System	10 Dec 2020 20:56:06
User entered '3'	System	16 Nov 2020 14:29:11
User entered '2'	System	12 Nov 2020 16:29:12
User entered '1'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
User entered '12/Nov/2020 16:29'	System	12 Nov 2020 16:29:12

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:28:47
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:06:13
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 16:29:12

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'USA-US065-2020-MRNA-1273-P301000002'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Michael'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Koren'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'US'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User entered '4'	System	10 Dec 2020 20:56:06
User entered '3'	System	16 Nov 2020 14:29:11
User entered '2'	System	12 Nov 2020 16:29:12
User entered '1'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '16/Nov/2020 14:29'	(b) (4) System	16 Nov 2020 14:29:11

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 20:55:54
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:29:11

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'USA-US065-2020-MRNA-1273-P301000002'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Yes (Y)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'No (N)'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Michael'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:10:39
User entered 'Koren'	System	05 Nov 2020 19:08:35

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:06:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:28:51
User entered 'US'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
	(b) (4)	
User entered '4'	System	10 Dec 2020 20:56:06
User entered '3'	System	16 Nov 2020 14:29:11
User entered '2'	System	12 Nov 2020 16:29:12
User entered '1'	System	05 Nov 2020 19:11:23

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered '10/Dec/2020 15:56'	(b) (4) System	10 Dec 2020 20:56:06

US3512193

Folder: SAE USA-US065-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:07:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:34:59
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 20:56:06